Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 321) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 8 days after the last dose of any study medication.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.96 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high creatinine [116 umol/L, range = (62 - 106)], high erythrocytes [6-8 /HPF, range = 0-5], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], normal protein [negative, range = NEGATIVE, BL =high], and high urate [482 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 321) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 61) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, prasugrel, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [45 U/L, range = (4 - 41)], high erythrocytes [6-8 /HPF, range = 0-5], high occult blood [1+, range = NEGATIVE], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 61) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 361) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: low bilirubin [2 umol/L, range = (3 - 21)], high glucose [7.7 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 342), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [7 umol/L, range = (3 - 21), BL =low], high creatine kinase [260 IU/L, range = (24 - 250), BL =normal], and high creatinine [113 umol/L, range = (62 - 106), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 361) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 684) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 95 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [9.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high occult blood [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [134 U/L, range = (40 - 129), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 684) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 304) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 51 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [22 umol/L, range = (3 - 21)], high glucose [9.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 162), the subject had the following on-study laboratory test results with results different than baseline:** high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and low hemoglobin [129 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 304) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): URINARY TRACT INFECTION [URINARY INFECTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 263) the subject experienced urinary tract infection [urinary infection] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and other medically important serious event. The event occurred 92 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the urinary tract infection and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatine kinase [365 IU/L, range = (20 - 203)], high lactate dehydrogenase [256 U/L, range = (5 - 250)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [41 IU/L, range = (20 - 203), BL =high], high erythrocytes [9-14 /HPF, range = 0-5, BL = missing], normal lactate dehydrogenase [123 U/L, range = (5 - 250), BL =high], high leukocytes [tntc /HPF, range = 0-3, BL =normal], high occult blood [2+, range = NEGATIVE, BL =normal], and high urate [422 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 263) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBRAL HAEMATOMA [CEREBRAL HEMATOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 262) the subject experienced cerebral haematoma [cerebral hematoma]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, and results in death. The event occurred 88 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebral haematoma and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, antidepressants, atorvastatin, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high glucose [18.2 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], high protein [2+, range = NEGATIVE], and low urate [143 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 262) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 847) the subject experienced cardiac failure acute [acute heart failure]. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 104 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, amoxicillin, ampicillin, atorvastatin, beta blocker, and levofloxacin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high creatinine [118 umol/L, range = (62 - 106)], and low glucose [4.2 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [4.9 mmol/L, range = (4.6 - 6.4), BL =low], and high urate [476 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 847) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE DECOMPENSATED HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 494) the subject experienced cardiac failure acute [acute decompensated heart failure]. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [22 umol/L, range = (3 - 21)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high glucose [8.2 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and low platelets [136 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [141 U/L, range = (40 - 129), BL =normal], normal blood urea nitrogen [6.78 mmol/L, range = (2.86 - 8.21), BL =high], high CRP [21.86 mg/L, range = (0 - 3), BL =normal], high direct bilirubin [9 umol/L, range = (0 - 5), BL =normal], normal glucose [4.8 mmol/L, range = (4.6 - 6.4), BL =high], high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5), BL =normal], and normal platelets [166 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 494) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE DECOMPENSATED HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 452) the subject experienced cardiac failure acute [acute decompensated heart failure]. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: acetylsalicylic acid, beta blocker, clopidogrel, hormone replacement therapy, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.36 mU/L, range = (0.55 - 4.78)], high calcium [2.6 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55)], and low glucose [4.2 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 334), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], normal calcium [2.48 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.48 mmol/L, range = (2.2 - 2.55), BL =high], and normal glucose [4.9 mmol/L, range = (4.6 - 6.4), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 452) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 585) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.12 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 554), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [7.32 mmol/L, range = (2.14 - 7.14), BL =normal], and low HbA1c [<0.041 fraction of 1, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 585) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 138) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [6.3 mU/L, range = (0.55 - 4.78)], and low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal hematocrit [0.43 fraction of 1, range = (0.4 - 0.52), BL =low].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 138) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 723) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [6-8 /HPF, range = 0-5], and high occult blood [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.71 mmol/L, range = (2.86 - 8.21), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 723) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 194) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 25 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [36 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [159 U/L, range = (40 - 129)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], high creatinine [170 umol/L, range = (62 - 106)], low glucose [3.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [8.21 mmol/L, range = (2.86 - 8.21), BL =high], high glucose [15.4 mmol/L, range = (4.6 - 6.4), BL =low], high glucose [3+, range = NEGATIVE, BL =normal], and low hemoglobin [123 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 194) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 606) the subject experienced pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 117 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatinine [85 umol/L, range = (44 - 80)], and low glucose [4.4 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 347), the subject had the following on-study laboratory test results with results different than baseline:** normal basophils [0.6 %, range = (0 - 2.4), BL = missing], normal basophils [0.03 10^9/L, range = (0 - 0.17), BL = missing], normal eosinophils [2.1 %, range = (0 - 6), BL = missing], normal eosinophils [0.12 10^9/L, range = (0 - 0.56), BL = missing], normal glucose [4.7 mmol/L, range = (4.6 - 6.4), BL =low], normal lymphocytes [38.9 %, range = (15.5 - 46.6), BL = missing], normal lymphocytes [2.26 10^9/L, range = (1.02 - 3.36), BL = missing], normal monocytes [5.5 %, range = (3.1 - 12.5), BL = missing], normal monocytes [0.32 10^9/L, range = (0.18 - 0.9), BL = missing], normal neutrophils [52.9 %, range = (40.9 - 77), BL = missing], and normal neutrophils [3.07 10^9/L, range = (2.03 - 8.36), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 606) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 146) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ezetimibe, and rosuvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline: high blood urea nitrogen [11.07 mmol/L, range = (2.14 - 7.14), BL =normal], and high creatinine [118 umol/L, range = (44 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 146) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 402) the subject experienced sudden cardiac death. The event was considered serious for the following reasons: results in death. The event occurred 66 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low creatine kinase [17 IU/L, range = (20 - 203)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], and normal creatine kinase [20 IU/L, range = (20 - 203), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 402) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [DEATH CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 589) the subject experienced cardiovascular disorder [death cardiovascular]. The event was considered serious for the following reasons: results in death. The event occurred 85 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [7.39 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatinine [92 umol/L, range = (44 - 80)], high erythrocytes [15-30 /HPF, range = 0-8], high glucose [7.2 mmol/L, range = (4.6 - 6.4)], high hematocrit [0.48 fraction of 1, range = (0.33 - 0.46)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high occult blood [3+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** normal hematocrit [0.4 fraction of 1, range = (0.33 - 0.46), BL =high], low platelets [125 10^9/L, range = (140 - 450), BL =normal], and high urate [553 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 589) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [PPD]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 789) the subject experienced death PPD] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 32 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ezetimibe, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [32 U/L, range = (4 - 31)], high CRP [7.92 mg/L, range = (0 - 3)], high creatine kinase [232 IU/L, range = (24 - 160)], high hematocrit [0.49 fraction of 1, range = (0.33 - 0.46)], high lactate dehydrogenase [280 U/L, range = (5 - 250)], low thyrotropin [0.35 mU/L, range = (0.55 - 4.78)], and high urate [387 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [29 U/L, range = (4 - 31), BL =high], high blood urea nitrogen [8.75 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [99 umol/L, range = (44 - 80), BL =normal], high erythrocytes [5.5 10^12/L, range = (3.8 - 5.4), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], normal leukocytes [4-12 /HPF, range = 0-12, BL = missing], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 789) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [DEATH ADMITTTED WITH M CVA AND DIED DURING ADMISSION.]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 299) the subject experienced cerebrovascular accident [death admittted with m cva and died during admission.] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.75 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.07 mmol/L, range = (2.86 - 8.21)], high creatinine [120 umol/L, range = (62 - 106)], and high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal hematocrit [0.49 fraction of 1, range = (0.37 - 0.5), BL =high], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 299) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SMALL CELL LUNG CANCER [SMALL CELL LUNG CARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 113) the subject experienced small cell lung cancer [small cell lung carcinoma] (Grade 3) and on PPD (Day 433) the subject died due to the event. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 82 days after the last dose of any study medication.

Concomitant medications taken at the onset of the small cell lung cancer and up to 30 days prior to event onset included: amoxycillin, augmentin duo forte, cefipime, and rosuvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline: low erythrocytes [3.4 10^12/L, range = (4 - 5.8), BL =normal], and low hemoglobin [126 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 433) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG ADENOCARCINOMA METASTATIC [DEATH DUE TO METASTATIC ADENOCARCINOMA OF THE LUNG.]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 452) the subject experienced lung adenocarcinoma metastatic [death due to metastatic adenocarcinoma of the lung.] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 129 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung adenocarcinoma metastatic and up to 30 days prior to event onset included: rosuvastatin, and unknown.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 452) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): POST PROCEDURAL HAEMORRHAGE [POST OPERATIVE BLEEDING - TISSUE AV REPLACEMENT AND MV REPAIR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 837) the subject experienced post procedural haemorrhage [post operative bleeding - tissue av replacement and mv repair] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 514 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the post procedural haemorrhage and up to 30 days prior to event onset included: amoxycillin, amoxylcillin, atorvastatin, and augmentin duo forte.

The subject had the following abnormal laboratory test results at baseline: low erythrocytes [3.6 10^12/L, range = (4 - 5.8)], low hemoglobin [123 g/L, range = (130 - 177)], high blood urea nitrogen [12.14 mmol/L, range = (2.86 - 8.21)], high creatinine [210 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [27 mL/min/1.73m2, range = (60 - 9999)], high glucose [7.9 mmol/L, range = (4.6 - 6.4)], high protein [trace, range = NEGATIVE], and high urate [684 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 837) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 155) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and ezetimibe.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 155) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 193) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: clopidogrel, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], and low hemoglobin [129 g/L, range = (130 - 175)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal hematocrit [0.4 fraction of 1, range = (0.4 - 0.52), BL =low], and normal hemoglobin [135 g/L, range = (130 - 175), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 193) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (PAD)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 302) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 49 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high CRP [18.37 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [12.55 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [23.92 mmol/L, range = (2.86 - 8.21)], high creatinine [166 umol/L, range = (62 - 106)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high urate [892 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.07 mmol/L, range = (2.86 - 8.21), BL =high], normal creatinine [103 umol/L, range = (62 - 106), BL =high], high glucose [9.9 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [120 g/L, range = (130 - 175), BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 302) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BRAIN INJURY [HYPOXIC BRAIN DAMAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 781) the subject experienced brain injury [hypoxic brain damage] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the brain injury and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, glycemic control medication, hormone replacement therapy, insulin, prasugrel, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.27 mg/L, range = (0 - 3)], high alkaline phosphatase [114 U/L, range = (35 - 104)], low creatine kinase [18 IU/L, range = (24 - 170)], high glucose [14.4 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-12], and high occult blood [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [98 U/L, range = (35 - 104), BL =high], high blood urea nitrogen [14.89 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [88 umol/L, range = (44 - 80), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], normal leukocytes [0-3 /HPF, range = 0-12, BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [690 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 781) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 450) the subject experienced cardiac failure [heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 119 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high protein [2+, range = NEGATIVE], high blood urea nitrogen [10 mmol/L, range = (2.14 - 7.14)], high creatinine [149 umol/L, range = (62 - 106)], high glucose [6.5 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [110 g/L, range = (130 - 175)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and low magnesium [0.5 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], normal magnesium [0.7 mmol/L, range = (0.65 - 1.05), BL =low], and high urate [678 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 450) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 237) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 71 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, fenofibrate, and omacor/lovaza.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.09 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], high creatinine [120 umol/L, range = (62 - 106)], and high urate [446 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5), BL =normal], and low hemoglobin [107 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 237) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 863) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 561 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, ezetimibe, hormone replacement therapy, oral corticosteroids, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.63 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.38 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [8.93 mmol/L, range = (2.14 - 7.14)], high creatinine [88 umol/L, range = (44 - 80)], low glucose [4.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [369 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 341), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [33 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [125 U/L, range = (35 - 104), BL =normal], low erythrocytes [3 10^12/L, range = (3.8 - 5.5), BL =normal], normal glucose [5.2 mmol/L, range = (4.6 - 6.4), BL =low], low hematocrit [0.26 fraction of 1, range = (0.35 - 0.47), BL =normal], low hemoglobin [82 g/L, range = (116 - 162), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], high lactate dehydrogenase [383 U/L, range = (5 - 250), BL =normal], high potassium [5.5 mmol/L, range = (3.3 - 5.1), BL =normal], low sodium [134 mmol/L, range = (135 - 147), BL =normal], and normal urate [262 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 863) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 473) the subject experienced carcinoid tumour pulmonary [pulmonary carcinoid tumor] (Grade 3) and on PPD (Day 606) the subject died. The event was considered serious for the following reasons: results in death. The event occurred 101 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, ciproflaxine, ciprofloxacine, ciprofloxine, clarithromycine, and proflox.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.27 mU/L, range = (0.55 - 4.78)], and high leukocytes [31-50 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [136 U/L, range = (40 - 129), BL =normal], high calcium [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high lactate dehydrogenase [320 U/L, range = (5 - 250), BL =normal], and normal leukocytes [0-3 /HPF, range = 0-3, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 606) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CHRONIC OBSTRUCTIVE PULMONARY DISEASE [COPD EXACERBATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 874) the subject experienced chronic obstructive pulmonary disease [copd exacerbation] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 33 days after the last dose of any study medication.

Concomitant medications taken at the onset of the chronic obstructive pulmonary disease and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, amoxiclav, atorvastatin, avelox, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [179 U/L, range = (4 - 33)], high alkaline phosphatase [237 U/L, range = (35 - 104)], high aspartate aminotransferase [88 U/L, range = (4 - 31)], high glucose [15.3 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], and high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [11 U/L, range = (4 - 33), BL =high], normal aspartate aminotransferase [9 U/L, range = (4 - 31), BL =high], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], low hematocrit [0.34 fraction of 1, range = (0.35 - 0.47), BL =normal], low hemoglobin [105 g/L, range = (116 - 162), BL =normal], high leukocytes [16.1 10^9/L, range = (4.1 - 12.3), BL =normal], high platelets [612 10^9/L, range = (140 - 450), BL =normal], and low urate [131 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 874) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 88) the subject was reported with myocardial infarction (Grade 4) and died. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatine kinase [458 IU/L, range = (20 - 203)], high glucose [7.1 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 88) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 46) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 45 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: angiotensin receptor blocker, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.45 mg/L, range = (0 - 3)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 46) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 370) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 369 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: meropenem, and simvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 184), the subject had the following on-study laboratory test results with results different than baseline: high glucose [1+, range = NEGATIVE, BL =normal], low hematocrit [0.4 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [123 g/L, range = (130 - 175), BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 370) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): AORTIC ANEURYSM [ABDOMINAL AORTIC ANEURYSM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 614) the subject experienced aortic aneurysm [abdominal aortic aneurysm] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the aortic aneurysm and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, angiotensin receptor blocker, atorvastatin, beta blocker, glycemic control medication, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high hepatitis A virus surface antibody [positive, range = NEGATIVE], high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], high glucose [6.9 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [119 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [60 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [49 U/L, range = (4 - 37), BL =normal], normal blood urea nitrogen [6.43 mmol/L, range = (2.14 - 7.14), BL =high], normal hematocrit [0.43 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [134 g/L, range = (130 - 175), BL =low], high protein [trace, range = NEGATIVE, BL =normal], and normal urate [327 umol/L, range = (202 - 416),

BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 614) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBRAL HAEMORRHAGE [HEMORRHAGE CEREBRAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 652) the subject experienced cerebral haemorrhage [hemorrhage cerebral] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 39 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebral haemorrhage and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.5 mmol/L, range = (2.86 - 8.21)], high CRP [6.3 mg/L, range = (0 - 3)], low calcium [2.08 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2.08 mmol/L, range = (2.2 - 2.55)], high creatinine [149 umol/L, range = (62 - 106)], and high glucose [10.7 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.48 mmol/L, range = (2.2 - 2.55), BL =low], normal calcium corrected [2.48 mmol/L, range = (2.2 - 2.55), BL =low], high glucose [1+, range = NEGATIVE, BL =normal], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06), BL = missing], low magnesium [0.56 mmol/L, range = (0.65 - 1.05), BL =normal], high potassium [5.5 mmol/L, range = (3.3 - 5.1), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 652) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DIARRHOEA [ABDOMINAL PAIN ASSOCIATED TO DIARREHA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 487) the subject experienced diarrhoea [abdominal pain associated to diarreha] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 196 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the diarrhoea and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [27.8 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [45 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [26.06 mmol/L, range = (2.86 - 8.21)], low calcium [2 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2 mmol/L, range = (2.2 - 2.55)], high creatinine [208 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [112 g/L, range = (130 - 177)], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 166), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [4 10^12/L, range = (4 - 5.8), BL =low], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], low leukocytes [3.7 10^9/L, range = (4.1 - 12.3), BL =normal], high potassium [5.5 mmol/L, range = (3.3 - 5.1), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and normal urate [387 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 487) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 398) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ciprofloxacin, simvastatin, and sulfametoxazol + trimetoprima.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [8.8 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high creatine kinase [207 IU/L, range = (20 - 203)], high creatinine [156 umol/L, range = (62 - 106)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [170 IU/L, range = (20 - 203), BL =high], and high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 398) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPTIC SHOCK [SEPTIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 332) the subject experienced septic shock (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 247 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [115 umol/L, range = (62 - 106), BL =normal], and high glucose [7.8 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 332) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 161) the subject experienced myocardial infarction (Grade 4) and on PPD (Day 176) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, beta blocker, clopidogrel, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.65 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [40 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [33 U/L, range = (35 - 104)], high creatinine [98 umol/L, range = (44 - 80)], low glucose [4.2 mmol/L, range = (4.6 - 6.4)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [446 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [114 U/L, range = (35 - 104), BL =low], normal glucose [5.6 mmol/L, range = (4.6 - 6.4), BL =low], high lactate dehydrogenase [403 U/L, range = (5 - 250), BL =normal], normal leukocytes [0-3 /HPF, range = 0-12, BL = missing], and normal potassium [4.7 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 176) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 676) the subject experienced pneumonia (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 52 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: amikacin, atorvastatin, cefepime, ertapenen, imipenem, simvastatin, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.85 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [28 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [144 U/L, range = (40 - 129)], high blood urea nitrogen [11.42 mmol/L, range = (2.14 - 7.14)], high creatinine [200 umol/L, range = (62 - 106)], low erythrocytes [3.7 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [119 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-3], high occult blood [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [16.7 mmol/L, range = (4.1 - 5.9), BL =normal], high glucose [2+, range = NEGATIVE, BL =normal], low magnesium [0.62 mmol/L, range = (0.65 - 1.05), BL =normal], high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal], high protein [86 g/L, range = (60 - 80), BL =normal], and low sodium [133 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 676) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SEPSIS [SEPSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 257) the subject experienced sepsis (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 18 days after the last dose of any study medication.

Concomitant medications taken at the onset of the sepsis and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [36 U/L, range = (40 - 129)], high creatinine [126 umol/L, range = (62 - 106)], low erythrocytes [3.4 10^12/L, range = (4 - 5.8)], low hematocrit [0.33 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [101 g/L, range = (130 - 177)], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], and low urate [178 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 174), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [40 U/L, range = (40 - 129), BL =low], low calcium [2.05 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.13 mmol/L, range = (2.2 - 2.55), BL =normal], normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high], and low sodium [129 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 257) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MULTIPLE ORGAN DYSFUNCTION SYNDROME [MULTIPLE ORGAN FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 352) the subject experienced multiple organ dysfunction syndrome [multiple organ failure] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 99 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the multiple organ dysfunction syndrome and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], low platelets [131 10^9/L, range = (140 - 450)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], low calcium [2.13 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2.13 mmol/L, range = (2.2 - 2.55)], high creatinine [136 umol/L, range = (62 - 106)], high erythrocytes [6.9 10^12/L, range = (4 - 5.8)], high glucose [7.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 177), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.23 mmol/L, range = (2.2 - 2.55), BL =low], normal calcium corrected [2.28 mmol/L, range = (2.2 - 2.55), BL =low], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], low glucose [4.3 mmol/L, range = (4.6 - 6.4), BL =high], low hemoglobin [110 g/L, range = (130 - 177), BL =normal], normal potassium [4.5 mmol/L, range = (3.3 - 5.1), BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 352) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ISCHAEMIC STROKE [ISCHEMIC STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 38) the subject experienced ischaemic stroke [ischemic stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 37 days after the last dose of any study medication.

Concomitant medications taken at the onset of the ischaemic stroke and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [31-50 /HPF, range = 0-12], high creatine kinase [300 IU/L, range = (24 - 160)], high creatinine [90 umol/L, range = (44 - 80)], high glucose [21.3 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 38) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 225) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 52 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.65 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [5.14 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high creatinine [100 umol/L, range = (44 - 80)], high direct bilirubin [7 umol/L, range = (0 - 5)], high glucose [21.3 mmol/L, range = (4.6 - 6.4)], high glucose [1+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high protein [trace, range = NEGATIVE], low sodium [133 mmol/L, range = (135 - 147)], and high urate [393 umol/L, range = (143 - 339)].
On the closest laboratory test results day on or prior to the start of the event (PPD Day 173), the subject had the following on-study laboratory test results with results different than baseline: low calcium [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], normal creatinine [76 umol/L, range = (44 - 80), BL =high], normal direct bilirubin [3 umol/L, range = (0 - 5), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], normal leukocytes [4-12 /HPF, range = 0-12, BL = missing], normal magnesium [0.7 mmol/L, range = (0.65 - 1.05), BL =low], normal protein [negative, range = NEGATIVE, BL =high], and normal sodium [136 mmol/L, range = (135 - 147), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 225) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH UNKNOWN CAUSE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 262) the subject experienced death [death unknown cause]. The event was considered serious for the following reasons: results in death. The event occurred 190 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.5 mg/L, range = (0 - 3)], low calcium [2.08 mmol/L, range = (2.1 - 2.58)], low calcium corrected [2.08 mmol/L, range = (2.1 - 2.58)], high creatine kinase [320 IU/L, range = (24 - 170)], high lactate dehydrogenase [263 U/L, range = (5 - 250)], high occult blood [1+, range = NEGATIVE], and high urate [351 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 262) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Non-Cardiovascular Procedure Or Surgery)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 388) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 135 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], high glucose [6 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 335), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.9 mmol/L, range = (4.1 - 5.9), BL =high], and normal urate [363 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 388) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACCUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 437) the subject experienced acute myocardial infarction [accute myocardial infarction]. The event was considered serious for the following reasons: results in death. The event occurred 83 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.5 mg/L, range = (0 - 3)], low hemoglobin [112 g/L, range = (116 - 162)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [351 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 354), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [10.5 mmol/L, range = (4.1 - 5.9), BL =normal], normal hemoglobin [117 g/L, range = (116 - 162), BL =low], and high leukocytes [31-50 /HPF, range = 0-12, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 437) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG CANCER METASTATIC [LUNG CANCER METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 158) the subject experienced lung cancer metastatic (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 157 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung cancer metastatic and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.65 mg/L, range = (0 - 3)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 83), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], and high glucose [9.8 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 158) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DENGUE FEVER [DENGUE HAEMORRHAGIC FEVER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 468) the subject experienced dengue fever [dengue haemorrhagic fever]. The event was considered serious for the following reasons: results in death. The event occurred 16 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the dengue fever and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glucose [4.4 mmol/L, range = (4.6 - 6.4)], high lactate dehydrogenase [600 U/L, range = (5 - 250)], and low potassium [3.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** normal basophils [0.4 %, range = (0 - 2.4), BL = missing], normal basophils [0.05 10^9/L, range = (0 - 0.17), BL = missing], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], normal eosinophils [0.2 %, range = (0 - 6), BL = missing], normal eosinophils [0.02 10^9/L, range = (0 - 0.56), BL = missing], normal lymphocytes [19 %, range = (15.5 - 46.6), BL = missing], normal lymphocytes [2.34 10^9/L, range = (1.02 - 3.36), BL = missing], normal monocytes [4.5 %, range = (3.1 - 12.5), BL = missing], normal monocytes [0.55 10^9/L, range = (0.18 - 0.9), BL = missing], normal neutrophils [75.9 %, range = (40.9 - 77), BL = missing], high neutrophils [9.34 10^9/L, range = (2.03 - 8.36), BL = missing], and normal potassium [3.7 mmol/L, range = (3.3 - 5.1), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 468) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 524) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4) and on PPD (Day 527) the subject experienced died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 22 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high creatinine [114 umol/L, range = (62 - 106)], and high potassium [5.5 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], low creatine kinase [22 IU/L, range = (24 - 250), BL =normal], normal creatinine [97 umol/L, range = (62 - 106), BL =high], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [119 g/L, range = (130 - 175), BL =normal], and normal potassium [4.6 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 527) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GASTRIC CANCER [GASTRIC CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 605) the subject experienced gastric cancer (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastric cancer and up to 30 days prior to event onset included: ACE inhibitor, beta blocker, clopidogrel, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [10.92 mU/L, range = (0.55 - 4.78)], and low erythrocytes [3.7 10^12/L, range = (3.8 - 5.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** low hematocrit [0.27 fraction of 1, range = (0.33 - 0.46), BL =normal], low hemoglobin [84 g/L, range = (110 - 161), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 605) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOGENIC SHOCK [CARDIOGENIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 267) the subject was reported with myocardial infarction (Grade 4) and on PPD (Day 267) the subject experienced cardiogenic shock (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiogenic shock and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, glycemic control medication, insulin, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: low calcium [2.15 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2.18 mmol/L, range = (2.2 - 2.55)], high creatinine [126 umol/L, range = (62 - 106)], low glucose [<2.2 mmol/L], high glucose [1+, range = NEGATIVE], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.2 mmol/L, range = (2.2 - 2.55), BL =low], normal calcium corrected [2.2 mmol/L, range = (2.2 - 2.55), BL =low], high glucose [6.6 mmol/L, range = (4.6 - 6.4), BL =low], normal glucose [negative, range = NEGATIVE, BL =high], and high hematocrit [0.52 fraction of 1, range = (0.37 - 0.5), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 267) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION ACUTE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 173) the subject experienced acute myocardial infarction [myocardial infarction acute] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.5 mg/L, range = (0 - 3)], high hematocrit [0.54 fraction of 1, range = (0.4 - 0.52)], high protein [trace, range = NEGATIVE], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal hematocrit [0.52 fraction of 1, range = (0.4 - 0.52), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and normal urate [363 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 173) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 658) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [18.49 mU/L, range = (0.55 - 4.78)], high creatine kinase [208 IU/L, range = (20 - 203)], high creatinine [108 umol/L, range = (62 - 106)], high protein [1+, range = NEGATIVE], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 512), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [171 U/L, range = (40 - 129), BL =normal], normal creatine kinase [178 IU/L, range = (20 - 203), BL =high], normal creatinine [99 umol/L, range = (62 - 106), BL =high], low erythrocytes [3.8 10^12/L, range = (4 - 5.8), BL =normal], low glucose [4.3 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [120 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [263 U/L, range = (5 - 250), BL =normal], low magnesium [0.61 mmol/L, range = (0.65 - 1.05), BL =normal], normal urate [286 umol/L, range = (202 - 416), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 658) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 583) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acenocoumerol, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high glucose [9.7 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 508), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [95 U/L, range = (4 - 41), BL =normal], low alkaline phosphatase [32 U/L, range = (40 - 129), BL =normal], high aspartate aminotransferase [81 U/L, range = (4 - 37), BL =normal], normal glucose [5.4 mmol/L, range = (4.6 - 6.4), BL =high], high protein [1+, range = NEGATIVE, BL =normal], and high ph [8.5, range = (5 - 8), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 583) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 449) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 23 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.21 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [38 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14)], high creatinine [163 umol/L, range = (62 - 106)], high protein [trace, range = NEGATIVE], and high urate [577 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 343), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.6 mmol/L, range = (4.1 - 5.9), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 449) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 824) the subject experienced cardiac failure acute [acute heart failure] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 12 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: atorvastatin, cephtriaxon natrium, and ciprinol.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.91 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], high creatinine [111 umol/L, range = (62 - 106)], high erythrocytes [9-14 /HPF, range = 0-5], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 666), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], high protein [trace, range = NEGATIVE, BL =normal], and high ph [8.5, range = (5 - 8), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 824) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 823) the subject experienced death [unknown cause of death]. The event was considered serious for the following reasons: results in death. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.13 mg/L, range = (0 - 3)], high glucose [6.2 mmol/L, range = (4.1 - 5.9)], high leukocytes [4-12 /HPF, range = 0-3], low magnesium [0.55 mmol/L, range = (0.65 - 1.05)], high protein [trace, range = NEGATIVE], and high urate [446 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 675), the subject had the following on-study laboratory test results with results different than baseline:** high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal leukocytes [0-3 /HPF, range = 0-3, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 823) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BLADDER CANCER [CARCINOMA URINARY BLADDER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 411) the subject experienced bladder cancer [carcinoma urinary bladder]. The event was considered serious for the following reasons: results in death. The event occurred 16 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the bladder cancer and up to 30 days prior to event onset included: atorvastatin, and ceftriaxone.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.21 mg/L, range = (0 - 3)], high thyrotropin [39.19 mU/L, range = (0.55 - 4.78)], high creatine kinase [206 IU/L, range = (20 - 203)], high leukocytes [31-50 /HPF, range = 0-3], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 340), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [53 IU/L, range = (20 - 203), BL =high], high creatinine [126 umol/L, range = (62 - 106), BL =normal], low hematocrit [0.31 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [95 g/L, range = (130 - 177), BL =normal], and normal potassium [4.3 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 411) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 494) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 77 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.19 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], high calcium [2.63 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55)], high creatinine [141 umol/L, range = (62 - 106)], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], and high urate [476 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [44 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [40 U/L, range = (4 - 37), BL =normal], normal blood urea nitrogen [7.53 mmol/L, range = (2.86 - 8.21), BL =high], normal calcium [2.44 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.43 mmol/L, range = (2.2 - 2.55), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 494) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 632) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 43 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.41 mg/L, range = (0 - 3)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], low platelets [98 10^9/L, range = (140 - 450)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.9 mmol/L, range = (4.6 - 6.4), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 632) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 409) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 276 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [26.43 mg/L, range = (0 - 3)], high thyrotropin [5.42 mU/L, range = (0.55 - 4.78)], high alanine aminotransferase [70 U/L, range = (4 - 41)], high aspartate aminotransferase [78 U/L, range = (4 - 37)], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 89), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [20 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [24 U/L, range = (4 - 37), BL =high], and normal glucose [6.2 mmol/L, range = (4.6 - 6.4), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 409) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 188) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, cipro xl, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [4-12 /HPF, range = 0-3], high bilirubin [1+, range = NEGATIVE], high occult blood [1+, range = NEGATIVE], low platelets [125 10^9/L, range = (140 - 450)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 164), the subject had the following on-study laboratory test results with results different than baseline:** low calcium [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], high erythrocytes [6-8 /HPF, range = 0-5, BL = missing], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 188) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULSELESS ELECTRICAL ACTIVITY [PULSELESS ELECTRICAL ACTIVITY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 456) the subject experienced pulseless electrical activity (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and other medically important serious event. The event occurred 120 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulseless electrical activity and up to 30 days prior to event onset included: acetylsalicylic acid, ancef, beta blocker, clopidogrel, glycemic control medication, hormone replacement therapy, insulin, keflex, rosuvastatin, and zithromax.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.23 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [8.1 mU/L, range = (0.55 - 4.78)], low thyroxine [11.2 pmol/L, range = (11.5 - 22.7)], low albumin [31 g/L, range = (35 - 52)], high alkaline phosphatase [108 U/L, range = (35 - 104)], high blood urea nitrogen [14.28 mmol/L, range = (2.86 - 8.21)], high creatine kinase [247 IU/L, range = (24 - 170)], high creatinine [194 umol/L, range = (44 - 80)], high glucose [8.2 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.34 fraction of 1, range = (0.35 - 0.47)], low hemoglobin [107 g/L, range = (116 - 162)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [262 U/L, range = (5 - 250)], high leukocytes [13.4 10^9/L, range = (4.1 - 12.3)], high leukocytes [31-50 /HPF, range = 0-12], high potassium [5.6

mmol/L, range = (3.3 - 5.1)], high protein [2+, range = NEGATIVE], and high urate [494 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 336), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [93 U/L, range = (35 - 104), BL =high], low bilirubin [2 umol/L, range = (3 - 21), BL =normal], low erythrocytes [3.4 10^12/L, range = (3.8 - 5.5), BL =normal], high glucose [trace, range = NEGATIVE, BL =normal], normal leukocytes [10.3 10^9/L, range = (4.1 - 12.3), BL =high], and normal leukocytes [0-3 /HPF, range = 0-12, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 456) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): COLON CANCER METASTATIC [METASTATIC COLON CANCER RESULTING IN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 216) the subject experienced colon cancer metastatic [metastatic colon cancer] (Grade 3) and on PPD (Day 249) the subject died due to the event. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 65 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the colon cancer metastatic and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [4-12 /HPF, range = 0-3], low platelets [125 10^9/L, range = (140 - 450)], high protein [2+, range = NEGATIVE], and high urate [482 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [141 U/L, range = (40 - 129), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], low glucose [4.3 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [345 U/L, range = (5 - 250), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], normal platelets [159 10^9/L, range = (140 - 450), BL =low], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 249) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 177) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 93 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [42.22 mg/L, range = (0 - 3)], high glucose [23.8 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-3], high protein [trace, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 84), the subject had the following on-study laboratory test results with results different than baseline:** low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52), BL =normal], and low hemoglobin [118 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 177) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 422) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 85 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.66 mg/L, range = (0 - 3)], high thyrotropin [5.39 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [125 umol/L, range = (62 - 106)], high glucose [7.9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [726 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [2.82 mg/L, range = (0 - 3), BL =high], low calcium [2.1 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.1 mmol/L, range = (2.2 - 2.55), BL =normal], normal creatinine [106 umol/L, range = (62 - 106), BL =high], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [114 g/L, range = (130 - 177), BL =normal], low magnesium [0.55 mmol/L, range = (0.65 - 1.05), BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 422) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ARRHYTHMIA [SUDDEN DEATH/ARRYTHMIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 812) the subject experienced arrhythmia [sudden death/arrythmia] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 741 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the arrhythmia and up to 30 days prior to event onset included: ACE inhibitor, analgesic or antipyretic agent, beta blocker, glycemic control medication, insulin, levofloxacin, mupirocin 2%, rosuvastatin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high creatinine [96 umol/L, range = (44 - 80)], high glucose [8.8 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 812) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [HYPOXEMIC RESPIRATORY INSUFFICIENCY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 582) the subject experienced respiratory failure [hypoxemic respiratory insufficiency]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: atorvastatin, and aura cefuroxime.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.21 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [32 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [5.59 mU/L, range = (0.55 - 4.78)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high creatinine [157 umol/L, range = (62 - 106)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high glucose [12 mmol/L, range = (4.6 - 6.4), BL =normal], high glucose [1+, range = NEGATIVE, BL =normal], high leukocytes [13-30 /HPF, range = 0-3, BL =normal], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [482 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 582) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 325) the subject experienced lung adenocarcinoma [adenocarcinoma of the lung] (Grade 4) and PPD (Day 605) the subject died due to the event. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 212 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, beta blocker, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.25 mg/L, range = (0 - 3)], high calcium [3.05 mmol/L, range = (2.2 - 2.55)], high calcium corrected [3.05 mmol/L, range = (2.2 - 2.55)], high creatine kinase [244 IU/L, range = (24 - 160)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [363 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high occult blood [trace, range = NEGATIVE, BL =normal], and normal urate [309 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 605) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ARRHYTHMIA [CARDIAC ARRHYTHMIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Ventricular Tachycardia)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 610) the subject experienced arrhythmia [cardiac arrhythmia] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 48 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the arrhythmia and up to 30 days prior to event onset included: atorvastatin, cipro, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high CRP [28.1 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], low blood urea nitrogen [2.14 mmol/L, range = (2.86 - 8.21)], high leukocytes [15 10^9/L, range = (4.1 - 12.3)], and high urate [399 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.35 mmol/L, range = (2.86 - 8.21), BL =low], high creatinine [105 umol/L, range = (44 - 80), BL =normal], high erythrocytes [9-14 /HPF, range = 0-8, BL = missing], high glucose [9.5 mmol/L, range = (4.6 - 6.4), BL =normal], high leukocytes [tntc /HPF, range = 0-12, BL =normal], high occult blood [1+, range = NEGATIVE, BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 610) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): COMPLETED SUICIDE [SUICIDE PPD]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Suicide)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 41) the subject experienced completed suicide [suicide (PPD)] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the completed suicide and up to 30 days prior to event onset included: acetylsalicylic acid, amoxicillin, analgesic or antipyretic agent, atorvastatin, ezetimibe, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 41) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ROAD TRAFFIC ACCIDENT PPD **]**

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 588) the subject experienced road traffic accident [PPD]. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 83 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the PPD and up to 30 days prior to event onset included: atorvastatin, and ezetimibe.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 588) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 341) the subject was reported with acute myocardial infarction [myocardial infarction acute] (Grade 4) and PPD (Day 341) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 312 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, antidepressants, atorvastatin, beta blocker, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.55 mg/L, range = (0 - 3)], high blood urea nitrogen [8.93 mmol/L, range = (2.14 - 7.14)], and low platelets [136 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 341) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIO RESPIRATORY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 927) the subject experienced cardio-respiratory arrest [cardio respiratory arrest] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [47 U/L, range = (4 - 41)], high aspartate aminotransferase [39 U/L, range = (4 - 37)], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], high creatinine [118 umol/L, range = (62 - 106)], and high sodium [148 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 838), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [14 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [16 U/L, range = (4 - 37), BL =high], normal blood urea nitrogen [8.03 mmol/L, range = (2.86 - 8.21), BL =high], and normal sodium [144 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 927) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [DEATH CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 591) the subject experienced cardiovascular disorder [death cardiovascular] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, amoxiciline, angiotensin receptor blocker, atorvastatin, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.57 mg/L, range = (0 - 3)], high glucose [17.4 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [63 U/L, range = (4 - 41), BL =normal], high lactate dehydrogenase [286 U/L, range = (5 - 250), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 591) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [DEATH- CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 614) the subject experienced cardiovascular disorder [death- cardiovascular] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 279 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [5.73 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [144 U/L, range = (40 - 129)], high creatine kinase [366 IU/L, range = (20 - 203)], high glucose [11.7 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 335), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [109 U/L, range = (40 - 129), BL =high], high creatinine [111 umol/L, range = (62 - 106), BL =normal], normal glucose [trace, range = NEGATIVE, BL =high], and high leukocytes [4-12 /HPF, range = 0-3, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 614) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GASTROINTESTINAL CARCINOMA [INTESTINAL CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 244) the subject experienced gastrointestinal carcinoma [intestinal cancer] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 75 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastrointestinal carcinoma and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.39 mg/L, range = (0 - 3)], high thyrotropin [5.18 mU/L, range = (0.55 - 4.78)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and low platelets [136 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 244) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [ACUTE PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 854) the subject experienced pneumonia [acute pneumonia]. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, and oral corticosteroids.

The subject had the following abnormal laboratory test results at baseline: high CRP [15.35 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], and high creatinine [88 umol/L, range = (44 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 848), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [29 g/L, range = (35 - 52), BL =normal], low calcium [1.93 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], high erythrocytes [9-14 /HPF, range = 0-8, BL = missing], low glucose [4.2 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [315 U/L, range = (5 - 250), BL =normal], high leukocytes [15 10^9/L, range = (4.1 - 12.3), BL =normal], high leukocytes [tntc /HPF, range = 0-12, BL =normal], low magnesium [0.5 mmol/L, range = (0.65 - 1.05), BL =normal], high occult blood [3+, range = NEGATIVE, BL =normal], low potassium [3.1 mmol/L, range = (3.3 - 5.1), BL =normal], and low protein [49 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 854) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 486) the subject experienced death (Grade 3). The event was considered serious for the following reasons: results in death. The event occurred 56 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and unknown.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.61 mg/L, range = (0 - 3)], high glucose [12.8 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [127 g/L, range = (130 - 175)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high occult blood [1+, range = NEGATIVE], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 343), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [negative, range = NEGATIVE, BL =high], and high leukocytes [4-12 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 486) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 340) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [32 umol/L, range = (3 - 21)], high direct bilirubin [7 umol/L, range = (0 - 5)], high occult blood [trace, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 330), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [45 U/L, range = (4 - 41), BL =normal], normal direct bilirubin [4 umol/L, range = (0 - 5), BL =high], normal HbA1c [0.05 fraction of 1, range = (0.04 - 0.06), BL = missing], normal occult blood [negative, range = NEGATIVE, BL =high], and high urate [428 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 340) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 225) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 224 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, cefoperazone sodium, ertapenem injection, fluconazole, and tazobactam sodium.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [34 umol/L, range = (3 - 21)], high direct bilirubin [7 umol/L, range = (0 - 5)], high lactate dehydrogenase [263 U/L, range = (5 - 250)], and high thyrotropin [4.98 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 164), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [128 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 225) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 264) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4) and on PPD (Day 477) the subject died due to the event. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 322 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [144 U/L, range = (40 - 129)], and low glucose [4.4 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 477) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 13) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.18 mg/L, range = (0 - 3)], high creatinine [116 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], and high urate [446 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 13) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 409) the subject experienced heart failure (Grade 4) and died. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 16 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, aztreonam, cefepime injection, erythromycin, and metronidazole.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [22 umol/L, range = (3 - 21)], high glucose [8.5 mmol/L, range = (4.6 - 6.4)], and high glucose [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 340), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [137 U/L, range = (40 - 129), BL =normal], normal bilirubin [18 umol/L, range = (3 - 21), BL =high], high blood urea nitrogen [9.92 mmol/L, range = (2.86 - 8.21), BL =normal], high CRP [12.72 mg/L, range = (0 - 3), BL =normal], high creatinine [111 umol/L, range = (62 - 106), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 409) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 175) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.9 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [48 U/L, range = (4 - 41), BL =normal], high bilirubin [22 umol/L, range = (3 - 21), BL =normal], and high blood urea nitrogen [8.07 mmol/L, range = (2.14 - 7.14), BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 175) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 249) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 24 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [8.4 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 249) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG INFECTION [PULMONARY INFECTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 212) the subject experienced lung infection [pulmonary infection] (Grade 4) and on PPD (Day 249) the subject died due to the event. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 24 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung infection and up to 30 days prior to event onset included: atorvastatin, cefoperazone sodium and sulbactam sodium, and tinidazole.

The subject had the following abnormal laboratory test results at baseline: high CRP [29.66 mg/L, range = (0 - 3)], high lactate dehydrogenase [303 U/L, range = (5 - 250)], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low creatinine [59 umol/L, range = (62 - 106), BL =normal], and normal urate [410 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 249) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 152) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 68 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [134 U/L, range = (35 - 104)], high creatinine [103 umol/L, range = (44 - 80)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], high protein [2+, range = NEGATIVE], and high urate [410 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 84), the subject had the following on-study laboratory test results with results different than baseline:** low potassium [3.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 152) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 482) the subject experienced sudden cardiac death. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 61 days after the last dose of any study medication.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, cefperazone-sulbactam, meropenem, and tinidazole.

The subject had the following abnormal laboratory test results at baseline: high CRP [21.25 mg/L, range = (0 - 3)], high occult blood [trace, range = NEGATIVE], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [2.69 mg/L, range = (0 - 3), BL =high], high glucose [7.7 mmol/L, range = (4.1 - 5.9), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 482) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [CEREBROVASCULAR ACCIDENT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 136) the subject experienced cerebrovascular accident (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, cefoxitin, and penicillin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high erythrocytes [6 10^12/L, range = (4 - 5.8)], high glucose [11.8 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high hematocrit [0.55 fraction of 1, range = (0.37 - 0.5)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high protein [2+, range = NEGATIVE], and high protein [81 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 84), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [50 U/L, range = (4 - 41), BL =normal], high bilirubin [27 umol/L, range = (3 - 21), BL =normal], normal erythrocytes [5.8 10^12/L, range = (4 - 5.8), BL =high], and normal protein [72 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 136) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL ISCHAEMIA [CARDIAC ISCHAEMIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 413) the subject experienced myocardial ischaemia [cardiac ischaemia] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 16 days after the last dose of any study medication.

Concomitant medications taken at the onset of the myocardial ischaemia and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, analgesic or antipyretic agent, angiotensin receptor blocker, atorvastatin, beta blocker, cefotiam, ceftazidime, clopidogrel, fluconazole, glycemic control medication, heparin, insulin, meropenem, sulbactam and cefoperazone, tazobactam sodium/piperacillin sodium, ticagrelor, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [128 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], and low glucose [4.2 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 347), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.53 mmol/L, range = (2.86 - 8.21), BL =normal], normal erythrocytes [4.1 10^12/L, range = (4 - 5.8), BL =low],

normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [7.1 mmol/L, range = (4.6 - 6.4), BL =low], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], high occult blood [1+, range = NEGATIVE, BL =normal], high protein [1+, range = NEGATIVE, BL =normal], and high urate [738 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 413) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 471) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 387 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: acetylsalicylic acid, analgesic or antipyretic agent, angiotensin receptor blocker, antidepressants, atorvastatin, atorvastatin, beta blocker, glycemic control medication, and hormone replacement therapy.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.23 mg/L, range = (0 - 3)], high aspartate aminotransferase [53 U/L, range = (4 - 31)], high glucose [9.5 mmol/L, range = (4.6 - 6.4)], low leukocytes [1.8 10^9/L, range = (4.1 - 12.3)], high protein [trace, range = NEGATIVE], low thyrotropin [0.2 mU/L, range = (0.55 - 4.78)], high creatinine [90 umol/L, range = (44 - 80)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and low magnesium [0.6 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 349), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [15 U/L, range = (4 - 31), BL =high], normal CRP [1.98 mg/L, range = (0 - 3), BL =high], normal leukocytes [8.4 10^9/L, range = (4.1 - 12.3), BL =low], and normal leukocytes [4-12 /HPF, range = 0-12, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 471) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 67) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 24 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high creatinine [99 umol/L, range = (44 - 80)], and high urate [446 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 67) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 323) the subject experienced glioblastoma multiforme [gliobastoma multiforme in the brain] (Grade 4) and on PPD (Day 361) the subject died. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 108 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high calcium [2.6 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal calcium [2.55 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.55 mmol/L, range = (2.2 - 2.55), BL =high], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], and normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 361) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 611) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 106 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and fraxiparin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [182 IU/L, range = (24 - 170)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [101 U/L, range = (4 - 33), BL =normal], high alkaline phosphatase [455 U/L, range = (35 - 104), BL =normal], high aspartate aminotransferase [111 U/L, range = (4 - 31), BL =normal], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21), BL =normal], normal creatine kinase [114 IU/L, range = (24 - 170), BL =high], high creatinine [105 umol/L, range = (44 - 80), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], high glucose [7 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [459 U/L, range = (5 - 250), BL =normal], normal leukocytes [0-3 /HPF, range = 0-12, BL = missing], high protein [1+, range = NEGATIVE, BL =normal], and high urate [399 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 611) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ADENOCARCINOMA PANCREAS [ADENOCARCINOMA PANCREAS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 205) the subject experienced adenocarcinoma pancreas (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 37 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the adenocarcinoma pancreas and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.73 mg/L, range = (0 - 3)], high glucose [10 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high urate [345 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [33 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [113 U/L, range = (35 - 104), BL =normal], low creatine kinase [11 IU/L, range = (24 - 160), BL =normal], high leukocytes [15.2 10^9/L, range = (4.1 - 12.3), BL =normal], and normal urate [303 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 205) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1146) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: amoxicilin/clavulanate, atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high calcium [2.63 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55)], high creatinine [117 umol/L, range = (62 - 106)], high glucose [9.5 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [14.35 mmol/L, range = (2.86 - 8.21), BL =normal], high leukocytes [13-30 /HPF, range = 0-3, BL =normal], high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [738 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1146) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BONE CANCER [BONE CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 994) the subject experienced bone cancer (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 420 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the bone cancer and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.7 mg/L, range = (0 - 3)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 512), the subject had the following on-study laboratory test results with results different than baseline:** high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal], and normal urate [404 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 994) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): METASTATIC NEOPLASM [METASTATIC CARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 464) the subject experienced metastatic neoplasm [metastatic carcinoma] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 22 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the metastatic neoplasm and up to 30 days prior to event onset included: atorvastatin, and augmentin (amoxicilin + klavulanat).

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [47 mL/min/1.73m2, range = (60 - 9999)], high creatinine [134 umol/L, range = (62 - 106)], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [14.87 mg/L, range = (0 - 3), BL =normal], low hemoglobin [129 g/L, range = (130 - 177), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high occult blood [1+, range = NEGATIVE, BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 464) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 174) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [9-14 /HPF, range = 0-5], high bilirubin [1+, range = NEGATIVE], high calcium [2.6 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58)], high protein [2+, range = NEGATIVE], high protein [81 g/L, range = (60 - 80)], and high urate [559 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.38 mmol/L, range = (2.1 - 2.58), BL =high], normal calcium corrected [2.38 mmol/L, range = (2.1 - 2.58), BL =high], low erythrocytes [3.8 10^12/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [126 g/L, range = (130 - 175), BL =normal], and normal protein [73 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 174) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): RENAL CELL CARCINOMA [GRAWITZ TUMOUR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1004) the subject experienced renal cell carcinoma [grawitz tumour]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, and results in death. The event occurred 57 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the renal cell carcinoma and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, beta blocker, ciplox 500mg, entizol, and medoxin 500mg.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.79 mg/L, range = (0 - 3)], high glucose [7.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], high protein [2+, range = NEGATIVE], and high urate [577 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** low calcium [2.09 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], high erythrocytes [31-50 /HPF, range = 0-5, BL =normal], low hemoglobin [124 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [322 U/L, range = (5 - 250), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], high occult blood [3+, range = NEGATIVE, BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and normal urate [280 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1004) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SQUAMOUS CELL CARCINOMA OF SKIN [SPINOCELLULAR CARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 671) the subject experienced squamous cell carcinoma of skin [spinocellular carcinoma]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, and results in death. The event occurred 77 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the squamous cell carcinoma of skin and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [219 U/L, range = (4 - 41)], high aspartate aminotransferase [123 U/L, range = (4 - 37)], high bilirubin [1+, range = NEGATIVE], high glucose [12.8 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low platelets [115 10^9/L, range = (140 - 450)], high protein [trace, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 507), the subject had the following on-study laboratory test results with results different than baseline:** low creatinine [57 umol/L, range = (62 - 106), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], normal platelets [153 10^9/L, range = (140 - 450), BL =low], and normal specific gravity [1.03, range = (1 - 1.04), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 671) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 522) the subject experienced sudden death [sudden death, cause unknown]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, angiotensin receptor blocker, atorvastatin, beta blocker, dabigatran, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.99 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.07 mmol/L, range = (2.14 - 7.14)], high creatinine [144 umol/L, range = (62 - 106)], high glucose [6.3 mmol/L, range = (4.1 - 5.9)], and high urate [535 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [42 U/L, range = (4 - 41), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 522) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH UNEXPLAINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 365) the subject experienced sudden death [sudden death unexplained] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 291 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, beta blocker, hormone replacement therapy, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.34 mg/L, range = (0 - 3)], and high urate [357 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high protein [1+, range = NEGATIVE, BL =normal], low sodium [133 mmol/L, range = (135 - 147), BL =normal], and normal urate [291 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 365) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 682) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 93 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, analgesic or antipyretic agent, angiotensin receptor blocker, antidepressants, atorvastatin, augmentin 1 g amoxicillin 875 mg and acid clavulanic 125 mg, augmentin 875 mg amoxicillin and 125 mg acid clavulanic, augmentin 875 mg amoxicillin and 125 mg acid clavulanic, beta blocker, biseptol 480 trimethoprim 80 mg, sulfamethoxazole 400 mg, ecalta anidulafungin 100 mg, fluconazole, fraxiparin, gentamicin lek gentamicin 80 mg/2ml, heparin, meropenem, meticillin, tazocin 4g / 0.25 g piperacillin 2 g and tazobactam 0.25 g, tygacil tigecycline 50mg, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.97 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [24 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [20.71 mmol/L, range = (2.86 - 8.21)], high creatine kinase [287 IU/L, range = (24 - 170)], high creatinine [244 umol/L, range = (44 - 80)], low erythrocytes [3.7 10^12/L, range = (3.8 - 5.5)], low hemoglobin [115 g/L, range = (116 - 162)], and high urate [488 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [109 IU/L, range = (24 - 170), BL =high], normal erythrocytes [4.1 10^12/L, range = (3.8 - 5.5), BL =low],

normal hemoglobin [125 g/L, range = (116 - 162), BL =low], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], high lactate dehydrogenase [255 U/L, range = (5 - 250), BL =normal], and normal urate [274 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 682) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPSIS [SEPSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 336) the subject experienced sepsis (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 83 days after the last dose of any study medication.

Concomitant medications taken at the onset of the sepsis and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [24.17 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high creatinine [113 umol/L, range = (62 - 106)], high leukocytes [16.6 10^9/L, range = (4.1 - 12.3)], high occult blood [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high erythrocytes [tntc /HPF, range = 0-5, BL = missing], high glucose [trace, range = NEGATIVE, BL =normal], high lactate dehydrogenase [303 U/L, range = (5 - 250), BL =normal], high leukocytes [31-50 /HPF, range = 0-3, BL =normal], and high urate [547 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 336) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 677) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 95 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [6.4 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [175 U/L, range = (35 - 104)], high creatinine [84 umol/L, range = (44 - 80)], high occult blood [trace, range = NEGATIVE], and high urate [381 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 512), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [49 U/L, range = (4 - 31), BL =normal], high lactate dehydrogenase [300 U/L, range = (5 - 250), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal], and normal urate [315 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 677) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SEPSIS [SEPSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 16) the subject experienced sepsis (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sepsis and up to 30 days prior to event onset included: atorvastatin, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [208 IU/L, range = (20 - 203)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 16) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 372) the subject experienced cardiac failure [heart failure (nos)] and died. The event was considered serious for the following reasons: results in death. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and zinnat.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [4-12 /HPF, range = 0-3], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and normal urate [416 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 372) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SQUAMOUS CELL CARCINOMA [SQUAMOUS CELL CARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 819) the subject experienced squamous cell carcinoma (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 115 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the squamous cell carcinoma and up to 30 days prior to event onset included: amoksiklav, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [11.2 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 704), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [122 g/L, range = (130 - 177), BL =normal], and low urate [143 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 819) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 38) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 37 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [38.47 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [157 U/L, range = (40 - 129)], high blood urea nitrogen [16.78 mmol/L, range = (2.86 - 8.21)], high calcium [2.58 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55)], high creatinine [158 umol/L, range = (62 - 106)], high glucose [13.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [325 U/L, range = (5 - 250)], high leukocytes [13.7 10^9/L, range = (4.1 - 12.3)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 38) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 211) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 122 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, ampicilin, analgesic or antipyretic agent, angiotensin receptor blocker, antidepressants, beta blocker, cefotaxine, clindamycin, enoxaparin, glycemic control medication, insulin, and unasyn.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.98 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [22 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [14.64 mmol/L, range = (2.14 - 7.14)], high creatinine [217 umol/L, range = (62 - 106)], high glucose [11.3 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [254 U/L, range = (5 - 250)], high occult blood [trace, range = NEGATIVE], high protein [3+, range = NEGATIVE], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 89), the subject had the following on-study laboratory test results with results different than baseline:** normal lactate dehydrogenase [250 U/L, range = (5 - 250), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 211) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): COLORECTAL CANCER METASTATIC [METASTATIC COLORECTAL CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 78) the subject experienced colorectal cancer metastatic [metastatic colorectal cancer] (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 21 days after the last dose of any study medication.

Concomitant medications taken at the onset of the colorectal cancer metastatic and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.71 mg/L, range = (0 - 3)], low thyrotropin [0.44 mU/L, range = (0.55 - 4.78)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 78) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 174) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.55 mg/L, range = (0 - 3)], high glucose [7.9 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [6.2 mmol/L, range = (4.6 - 6.4), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 174) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CONDITION AGGRAVATED [DISEASE AGGRAVATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 635) the subject experienced condition aggravated [disease aggravation]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 129 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the condition aggravated and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.89 mg/L, range = (0 - 3)], high glucose [8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high leukocytes [13-30 /HPF, range = 0-12], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal leukocytes [0-3 /HPF, range = 0-12, BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 635) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): RENAL CANCER [ILL DIED ON THE PROGRESSION OF KIDNEY CANCER.]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 233) the subject experienced renal cell carcinoma [grawitz tumor] (Grade 3) and on PPD (Day 330) the subject died due to the progression of kidney cancer. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 135 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.47 mg/L, range = (0 - 3)], high creatine kinase [269 IU/L, range = (24 - 250)], high glucose [6.5 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [126 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21), BL =normal], normal creatine kinase [52 IU/L, range = (24 - 250), BL =high], high creatinine [134 umol/L, range = (62 - 106), BL =normal], high glucose [trace, range = NEGATIVE, BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and high potassium [5.5 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 330) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 69) the subject experienced cardiac failure [heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high calcium [2.68 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.68 mmol/L, range = (2.2 - 2.55)], high creatinine [117 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high glucose [10 mmol/L, range = (4.6 - 6.4)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], high glucose [1+, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 69) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 232) the subject experienced bronchial carcinoma [bronchogenic carcinoma] (Grade 4) and on PPD (Day 550) the subject died due to the event. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 311 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.57 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high creatinine [122 umol/L, range = (62 - 106)], low erythrocytes [3.7 10^12/L, range = (4 - 5.8)], low hemoglobin [124 g/L, range = (130 - 177)], low magnesium [0.5 mmol/L, range = (0.65 - 1.05)], high protein [2+, range = NEGATIVE], and high urate [577 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 168), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 550) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 259) the subject was reported with myocardial infarction (Grade 4) and on PPD (Day 259) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, antidepressants, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.71 mg/L, range = (0 - 3)], and high alkaline phosphatase [126 U/L, range = (35 - 104)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 174), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and high urate [357 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 259) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 222) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [9.7 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high calcium [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], high hematocrit [0.52 fraction of 1, range = (0.37 - 0.5), BL =normal], and high protein [85 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 222) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [PULMONARY CARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 252) the subject experienced lung neoplasm malignant [pulmonary carcinoma] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 27 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.23 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.8 10^12/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.34 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [119 g/L, range = (130 - 175), BL =normal], and low leukocytes [3.4 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 252) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 651) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, augmentin 1g, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14)], high creatinine [113 umol/L, range = (62 - 106)], high erythrocytes [6.4 10^12/L, range = (4.1 - 5.9)], high glucose [6.8 mmol/L, range = (4.1 - 5.9)], high hematocrit [0.57 fraction of 1, range = (0.4 - 0.52)], high hemoglobin [177 g/L, range = (130 - 175)], high leukocytes [4-12 /HPF, range = 0-3], and high potassium [6 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 514), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [4.28 mmol/L, range = (2.14 - 7.14), BL =high], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], normal creatinine [78 umol/L, range = (62 - 106), BL =high], normal hematocrit [0.51 fraction of 1, range = (0.4 - 0.52), BL =high], normal hemoglobin [161 g/L, range = (130 - 175), BL =high], high platelets [600 10^9/L, range = (140 - 450), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 651) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 840) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, ofloxacin, spersadex, and tobradex.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.65 mg/L, range = (0 - 3)], high creatine kinase [217 IU/L, range = (20 - 203)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 840) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GASTRIC CANCER [GASTRIC CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 437) the subject experienced gastric cancer (Grade 3) and on PPD (Day 640) the subject died due to gastric cancer. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 65 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastric cancer and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [113 U/L, range = (35 - 104)], and high creatinine [84 umol/L, range = (44 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 640) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1019) the subject experienced death [unknown cause of death]. The event was considered serious for the following reasons: results in death. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, beta blocker, glycemic control medication, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high glucose [9.1 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [33 umol/L, range = (3 - 21), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1019) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ILEUS [ILEUS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 285) the subject experienced ileus (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 11 days after the last dose of any study medication.

Concomitant medications taken at the onset of the ileus and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.87 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], high creatinine [156 umol/L, range = (62 - 106)], high glucose [6.5 mmol/L, range = (4.6 - 6.4)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and high occult blood [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 285) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [BRONCHOPNEUMONIA, ORGANISM UNSPECIFIED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 262) the subject experienced pneumonia [bronchopneumonia, organism unspecified] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 13 days after the last dose of any study medication.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, amoxicillin, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, clopidogrel, cotrimoxazol, enoxaparin, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.38 mg/L, range = (0 - 3)], high direct bilirubin [7 umol/L, range = (0 - 5)], high glucose [19.4 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.14 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low alkaline phosphatase [37 U/L, range = (40 - 129), BL =normal], high bilirubin [1+, range = NEGATIVE, BL =normal], normal direct bilirubin [3 umol/L, range = (0 - 5), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], low hemoglobin [125 g/L, range = (130 - 177), BL =normal], and low magnesium [0.45 mmol/L, range = (0.65 - 1.05), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 262) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG CARCINOMA CELL TYPE UNSPECIFIED STAGE IV [LUNG CARCINOMA CELL TYPE UNSPECIFIED STAGE IV]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 237) the subject experienced non-small cell lung cancer [generalized lung non small cell lung carcinoma] (Grade 4) and on PPD (Day 257) the subject died due to lung carcinoma cell type unspecified stage iv (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 88 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung carcinoma cell type unspecified stage iv and up to 30 days prior to event onset included: atorvastatin, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.8 mmol/L, range = (4.1 - 5.9)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.4 mmol/L, range = (4.1 - 5.9), BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 257) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 291) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 290 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [176 IU/L, range = (24 - 160)], and high urate [399 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [96 IU/L, range = (24 - 160), BL =high], high creatinine [82 umol/L, range = (44 - 80), BL =normal], normal leukocytes [4-12 /HPF, range = 0-12, BL = missing], and high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal].

Action taken with IP and statin was not reported.The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 291) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 901) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 32 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.13 mg/L, range = (0 - 3)], high alkaline phosphatase [122 U/L, range = (35 - 104)], and low potassium [3 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [72 U/L, range = (35 - 104), BL =high], high blood urea nitrogen [9.39 mmol/L, range = (2.86 - 8.21), BL =normal], and normal potassium [3.5 mmol/L, range = (3.3 - 5.1), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 901) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC DEATH [CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 228) the subject experienced cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac death and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.07 mg/L, range = (0 - 3)], and high creatine kinase [320 IU/L, range = (20 - 203)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [40 U/L, range = (4 - 37), BL =normal], high bilirubin [22 umol/L, range = (3 - 21), BL =normal], high blood urea nitrogen [12.5 mmol/L, range = (2.86 - 8.21), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], low hemoglobin [127 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [258 U/L, range = (5 - 250), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], low platelets [135 10^9/L, range = (140 - 450), BL =normal], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], high protein [3+, range = NEGATIVE, BL =normal], and high urate [422 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 228) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 470) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 52 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, antidepressants, atorvastatin, beta blocker, ezetimibe, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.25 mg/L, range = (0 - 3)], low hemoglobin [126 g/L, range = (130 - 175)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and low urate [196 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 342), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal CRP [1.12 mg/L, range = (0 - 3), BL =high], high glucose [7.2 mmol/L, range = (4.6 - 6.4), BL =normal], normal hemoglobin [130 g/L, range = (130 - 175), BL =low], high protein [trace, range = NEGATIVE, BL =normal], and normal urate [244 umol/L, range = (202 - 416), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 470) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): INTRACRANIAL HAEMATOMA [INTRACRANIAL HAEMATOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 510) the subject experienced intracranial haematoma (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 33 days after the last dose of any study medication.

Concomitant medications taken at the onset of the intracranial haematoma and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, amoksiklav, atorvastatin, azitrox, beta blocker, ezetimibe, glycemic control medication, klacid, rivaroxaban, and sefotak.

The subject had the following abnormal laboratory test results at baseline: high CRP [15.64 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [132 umol/L, range = (62 - 106)], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [553 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 508), the subject had the following on-study laboratory test results with results different than baseline:** low calcium [2.16 mmol/L, range = (2.2 - 2.55), BL =normal], high erythrocytes [tntc /HPF, range = 0-5, BL =normal], high glucose [1+, range = NEGATIVE, BL =normal], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [104 g/L,

range = (130 - 177), BL =normal], high leukocytes [16.1 10^9/L, range = (4.1 - 12.3), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high occult blood [3+, range = NEGATIVE, BL =normal], and low sodium [134 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 510) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 57) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, fenofibrate, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high creatinine [172 umol/L, range = (62 - 106)], high glucose [17.9 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 57) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG CANCER METASTATIC [LUNG CANCER METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 337) the subject experienced non-small cell lung cancer (Grade 3) and on PPD (Day 633) the subject died from lung cancer metastatic (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 40 days after the last dose of any study medication.

Concomitant medications taken at the onset of the lung cancer metastatic and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [12.9 10^9/L, range = (4.1 - 12.3)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [110 U/L, range = (35 - 104), BL =normal], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [118 umol/L, range = (44 - 80), BL =normal], low erythrocytes [2.9 10^12/L, range = (3.8 - 5.4), BL =normal], low hematocrit [0.27 fraction of 1, range = (0.33 - 0.46), BL =normal], low hemoglobin [90 g/L, range = (110 - 161), BL =normal], high lactate dehydrogenase [347 U/L, range = (5 - 250), BL =normal], low leukocytes [2.6 10^9/L, range = (4.1 - 12.3), BL =high], low magnesium [0.45 mmol/L, range = (0.65 - 1.05), BL =normal], high metamyelocytes [2 %, range = (0 - 0), BL = missing], normal neutrophils band form [2 %, range = (0 - 5), BL = missing], high nucleated erythrocytes [3 /100 WBC, range = (0 - 1), BL = missing], low platelets [51 10^9/L, range = (140 - 450), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and high urate [404 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 633) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Renal)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 164) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 79 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high creatinine [93 umol/L, range = (44 - 80)], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], high leukocytes [15.2 10^9/L, range = (4.1 - 12.3)], low magnesium [0.5 mmol/L, range = (0.65 - 1.05)], high platelets [581 10^9/L, range = (140 - 450)], and low sodium [132 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 164) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CHOLANGIOCARCINOMA [CHOLANGIOCARCINOMA METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 444) the subject experienced cholangiocarcinoma [cholangiocarcinoma metastatic] (Grade 4) and PPD (Day 598) the subject died due to cholangiocarcinoma [cholangiocarcinoma metastatic] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 30 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cholangiocarcinoma and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.66 mg/L, range = (0 - 3)], high alkaline phosphatase [134 U/L, range = (40 - 129)], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [128 g/L, range = (130 - 175)], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 498), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], normal urate [381 umol/L, range = (202 - 416), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 598) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 312) the subject experienced sudden death [sudden death, cause unknown]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, and results in death. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high creatinine [129 umol/L, range = (62 - 106)], high glucose [13.4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [31-50 /HPF, range = 0-3], high occult blood [trace, range = NEGATIVE], and high urate [714 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 175), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [132 U/L, range = (40 - 129), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], normal occult blood [negative, range = NEGATIVE, BL =high], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 312) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE RESPIRATORY DISTRESS SYNDROME [ACUTE RESPIRATORY DISTRESS SYNDROME]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 426) the subject experienced acute respiratory distress syndrome (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 33 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute respiratory distress syndrome and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline: low calcium [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], and low calcium corrected [2.15 mmol/L, range = (2.2 - 2.55), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 426) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PANCREATITIS [PANCREATITIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pancreatic)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 494) the subject experienced pancreatitis (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pancreatitis and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [15-30 /HPF, range = 0-5], high leukocytes [13-30 /HPF, range = 0-3], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high occult blood [2+, range = NEGATIVE], and high urate [446 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.8 10^12/L, range = (4 - 5.8), BL =normal], high glucose [7.9 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [124 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [277 U/L, range = (5 - 250), BL =normal], normal magnesium [0.75 mmol/L, range = (0.65 - 1.05), BL =low], high sodium [148 mmol/L, range = (135 - 147), BL =normal], and normal urate [369 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 494) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 554) the subject experienced combined pulmonary fibrosis and emphysema (Grade 4) and on PPD (Day 676) the subject died. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [46.57 mg/L, range = (0 - 3)], low creatinine [56 umol/L, range = (62 - 106)], high glucose [7 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [0.97 mg/L, range = (0 - 3), BL =high], normal creatinine [64 umol/L, range = (62 - 106), BL =low], high urate [452 umol/L, range = (202 - 416), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 676) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 366) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 25 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [13.57 mmol/L, range = (2.86 - 8.21)], high creatinine [150 umol/L, range = (62 - 106)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], high sodium [148 mmol/L, range = (135 - 147)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 341), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high lactate dehydrogenase [360 U/L, range = (5 - 250), BL =normal], high leukocytes [14.1 10^9/L, range = (4.1 - 12.3), BL =normal], normal potassium [4.8 mmol/L, range = (3.3 - 5.1), BL =high], and normal sodium [147 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 366) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 93) the subject experienced sudden death [sudden death, cause unknown] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [13-30 /HPF, range = 0-3], high protein [1+, range = NEGATIVE], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 93) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [ACUTE MASSIVE PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Pulmonary Embolism)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 610) the subject experienced pulmonary embolism [acute massive pulmonary embolism] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: ACE inhibitor, beta blocker, clopidogrel, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.71 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], high creatinine [114 umol/L, range = (62 - 106)], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], high protein [2+, range = NEGATIVE], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than**

baseline: high calcium [2.59 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06), BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and normal urate [369 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 610) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [BRONCHOPNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 345) the subject experienced pneumonia [bronchopneumonia] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 106 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, beta blocker, fraxiparin, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.66 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [87 umol/L, range = (44 - 80), BL =normal], low erythrocytes [2.8 10^12/L, range = (3.8 - 5.4), BL =normal], high glucose [6.5 mmol/L, range = (4.6 - 6.4), BL =normal], low hematocrit [0.28 fraction of 1, range = (0.33 - 0.46), BL =normal], low hemoglobin [97 g/L, range = (110 - 161), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], high lactate dehydrogenase [260 U/L, range = (5 - 250), BL =normal], and high urate [351 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 345) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): NEPHROPATHY [RENAL DISEASE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 594) the subject experienced renal failure [kidney failure] (Grade 4) and on PPD (Day 595) the subject died due to nephropathy [renal disease] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 251 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the nephropathy and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, beta blocker, glycemic control medication, and ticlopidine.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline: low glucose [3.9 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [129 g/L, range = (130 - 177), BL =normal], and low urate [172 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 595) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [CARCINOMA OF LUNG]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 359) the subject experienced lung neoplasm malignant [carcinoma of lung] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 78 days after the last dose of any study medication.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: apo flukonazol 400 mg ráno, augmentin, betalactam, klacid, normix, ofloxin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.73 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high protein [trace, range = NEGATIVE], and high urate [446 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [696 IU/L, range = (20 - 203), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 359) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MENINGITIS PNEUMOCOCCAL [MENINGITIS BACTERIAL (PNEUMOCOC)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 75) the subject experienced meningitis pneumococcal [meningitis bacterial (pneumococ)] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 18 days after the last dose of any study medication.

Concomitant medications taken at the onset of the meningitis pneumococcal and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [104.52 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [39 U/L, range = (4 - 33)], high aspartate aminotransferase [37 U/L, range = (4 - 31)], high bilirubin [22 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatine kinase [468 IU/L, range = (24 - 160)], high creatinine [107 umol/L, range = (44 - 80)], high direct bilirubin [7 umol/L, range = (0 - 5)], high protein [trace, range = NEGATIVE], and high urate [446 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 75) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): NON-SMALL CELL LUNG CANCER STAGE III [LUNG CANCER NON-SMALL CELL STAGE III]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 489) the subject experienced non-small cell lung cancer stage iii [lung cancer non-small cell stage iii] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 235 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the non-small cell lung cancer stage iii and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [12.04 mg/L, range = (0 - 3)], high creatine kinase [364 IU/L, range = (24 - 250)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 268), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [109 IU/L, range = (24 - 250), BL =high], high glucose [6.8 mmol/L, range = (4.1 - 5.9), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 489) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIOGENIC SHOCK [CARDIOGENIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 120) the subject experienced cardiogenic shock (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 64 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiogenic shock and up to 30 days prior to event onset included: atorvastatin, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: low albumin [33 g/L, range = (35 - 52)], high blood urea nitrogen [11.42 mmol/L, range = (2.86 - 8.21)], low calcium [2.18 mmol/L, range = (2.2 - 2.55)], high creatinine [169 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [35 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [4.93 mU/L, range = (0.55 - 4.78)], high glucose [trace, range = NEGATIVE], low hemoglobin [126 g/L, range = (130 - 177)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high occult blood [1+, range = NEGATIVE], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [60 U/L, range = (4 - 37), BL =normal], high bilirubin [39 umol/L, range = (3 - 21), BL =normal], normal calcium [2.35 mmol/L, range = (2.2 - 2.55), BL =low], and high direct bilirubin [27 umol/L, range = (0 - 5), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 120) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 172) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, apixaban, atorvastatin, beta blocker, fenofibrate, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high glucose [11.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], and low urate [149 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 164), the subject had the following on-study laboratory test results with results different than baseline:** normal protein [negative, range = NEGATIVE, BL =high], and normal urate [214 umol/L, range = (202 - 416), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 172) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 550) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 45 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [7.3 mmol/L, range = (4.6 - 6.4), BL =normal], and high urate [375 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 550) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [DISSEMINATED LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 755) the subject experienced lung neoplasm malignant [disseminated lung cancer] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 82 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: ACE inhibitor, analgesic or antipyretic agent, atorvastatin, clavithromycin, clopidogrel, glycemic control medication, meropenem, oral corticosteroids, unknown antibiotics, and zinacef.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.65 mg/L, range = (0 - 3)], high glucose [7.4 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high leukocytes [15.2 10^9/L, range = (4.1 - 12.3)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [293 U/L, range = (40 - 129), BL =normal], high lactate dehydrogenase [446 U/L, range = (5 - 250), BL =normal], and low sodium [134 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 755) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEAD ON ARRIVAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 825) the subject experienced death [dead on arrival] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 20 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], high specific gravity [1.04, range = (1 - 1.04)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 674), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], normal protein [negative, range = NEGATIVE, BL =high], and normal specific gravity [1.02, range = (1 - 1.04), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 825) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 126) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [41 U/L, range = (4 - 37)], high bilirubin [29 umol/L, range = (3 - 21)], high creatine kinase [471 IU/L, range = (20 - 203)], and high direct bilirubin [7 umol/L, range = (0 - 5)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [36 U/L, range = (4 - 37), BL =high], normal bilirubin [14 umol/L, range = (3 - 21), BL =high], and normal direct bilirubin [5 umol/L, range = (0 - 5), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 126) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 636) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.25 mg/L, range = (0 - 3)], high creatinine [111 umol/L, range = (62 - 106)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [589 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [103 umol/L, range = (62 - 106), BL =high], and high glucose [6.5 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 636) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NATURAL CAUSE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 724) the subject was reported with myocardial infarction [myocardiel infarction] (Grade 4) and on PPD (Day 724) the subject experienced death [death natural cause] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.59 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [42 U/L, range = (4 - 33)], high alkaline phosphatase [108 U/L, range = (35 - 104)], high aspartate aminotransferase [35 U/L, range = (4 - 31)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high creatinine [97 umol/L, range = (44 - 80)], high leukocytes [12.4 10^9/L, range = (4.1 - 12.3)], and high urate [381 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.57 mmol/L, range = (2.86 - 8.21), BL =high], high hematocrit [0.48 fraction of 1, range = (0.35 - 0.47), BL =normal], normal leukocytes [11.1 10^9/L, range = (4.1 - 12.3), BL =high], and normal urate [303 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 724) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 233) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 64 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], low glucose [4.5 mmol/L, range = (4.6 - 6.4)], high protein [trace, range = NEGATIVE], and high urate [476 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [5.36 mmol/L, range = (2.86 - 8.21), BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 233) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 425) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 368 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: analgesic or antipyretic agent, atorvastatin, bioclavid, cefuroxim, ciprofloxacin, gentamycin, hexamycin, meropenem, metronidazol, penomax, piperacil/tazobac, and piperacil/tazobac stragen.

The subject had the following abnormal laboratory test results at baseline: high urate [470 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 425) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 344) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 343 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [49 U/L, range = (4 - 37)], and high urate [547 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 343), the subject had the following on-study laboratory test results with results different than baseline:** high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 344) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 50) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 20 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.71 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [35 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatinine [146 umol/L, range = (62 - 106)], low hemoglobin [123 g/L, range = (130 - 177)], and high urate [726 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 50) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 827) the subject experienced sudden cardiac death. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 113 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high creatinine [120 umol/L, range = (62 - 106)], low hemoglobin [125 g/L, range = (130 - 177)], low leukocytes [3.9 10^9/L, range = (4.1 - 12.3)], high leukocytes [tntc /HPF, range = 0-3], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal hemoglobin [140 g/L, range = (130 - 177), BL =low], normal leukocytes [4.7 10^9/L, range = (4.1 - 12.3), BL =low], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 827) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 365) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 364 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, glycemic control medication, and rivaroxaban.

The subject had the following abnormal laboratory test results at baseline: low hemoglobin [123 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [111 umol/L, range = (62 - 106), BL =normal], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 365) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 636) the subject experienced death (Grade 4). The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.9 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low platelets [91 10^9/L, range = (140 - 450)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [234 IU/L, range = (20 - 203), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], normal protein [negative, range = NEGATIVE, BL =high], and high urate [434 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 636) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 108) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, atorvastatin, beta blocker, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low alkaline phosphatase [35 U/L, range = (40 - 129)], low creatinine [51 umol/L, range = (62 - 106)], and low urate [190 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 86), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [52 U/L, range = (40 - 129), BL =low], normal creatinine [80 umol/L, range = (62 - 106), BL =low], and normal urate [375 umol/L, range = (202 - 416), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 108) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUBARACHNOID HAEMORRHAGE [SUBARACHNOIDAL HEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 673) the subject experienced subarachnoid haemorrhage [subarachnoidal hemorrhage] (Grade 4). The event occurred 84 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the subarachnoid haemorrhage and up to 30 days prior to event onset included: atorvastatin, and unasyn.

The subject had the following abnormal laboratory test results at baseline: high CRP [15.22 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high creatinine [108 umol/L, range = (44 - 80)], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], high lactate dehydrogenase [253 U/L, range = (5 - 250)], high leukocytes [13-30 /HPF, range = 0-12], low magnesium [0.45 mmol/L, range = (0.65 - 1.05)], high occult blood [trace, range = NEGATIVE], high protein [2+, range = NEGATIVE], and high urate [387 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high calcium [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], normal lactate dehydrogenase [163 U/L, range = (5 - 250), BL =high], normal leukocytes [0-3 /HPF, range = 0-12, BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], and normal urate [297 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 673) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 105) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 16 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 89), the subject had the following on-study laboratory test results with results different than baseline: high leukocytes [16.7 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 105) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 655) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 497 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 178), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [88 umol/L, range = (44 - 80), BL =normal], and high urate [369 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 655) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 200) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.96 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], normal bilirubin [negative, range = NEGATIVE, BL =high], low creatinine [56 umol/L, range = (62 - 106), BL =normal], and high leukocytes [14.8 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 200) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): EPILEPSY [EPILEPSY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Neurological)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 720) the subject experienced epilepsy (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 82 days after the last dose of any study medication.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.92 mg/L, range = (0 - 3)], high direct bilirubin [7 umol/L, range = (0 - 5)], low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [79 U/L, range = (4 - 41)], high alkaline phosphatase [631 U/L, range = (40 - 129)], high aspartate aminotransferase [103 U/L, range = (4 - 37)], high bilirubin [26 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high creatine kinase [365 IU/L, range = (20 - 203)], low glucose [4.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [15 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [17 U/L, range = (4 - 37), BL =high], normal creatine kinase [69 IU/L, range = (20 - 203), BL =high], normal glucose [5.8 mmol/L, range = (4.6 - 6.4), BL =low], and low hemoglobin [126 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 720) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 69) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 69) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 664) the subject was reported with ventricular fibrillation (Grade 4) and on PPD (Day 664) the subject experienced sudden cardiac death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: amoxicilline, atorvastatin, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [55 U/L, range = (4 - 41)], high aspartate aminotransferase [38 U/L, range = (4 - 37)], high blood urea nitrogen [8.93 mmol/L, range = (2.14 - 7.14)], high glucose [8 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low platelets [120 10^9/L, range = (140 - 450)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 501), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [35 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [34 U/L, range = (4 - 37), BL =high], high calcium [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [541 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 664) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUICIDE ATTEMPT [ATTEMPTED SUICIDE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Suicide)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 525) the subject experienced suicide attempt [attempted suicide] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the suicide attempt and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, antidepressants, beta blocker, ezetimibe, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [348 IU/L, range = (24 - 250)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 512), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [111 umol/L, range = (62 - 106), BL =normal], high glucose [6.2 mmol/L, range = (4.1 - 5.9), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and high urate [428 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 525) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 922) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 70 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.95 mg/L, range = (0 - 3)], high glucose [trace, range = NEGATIVE], low platelets [89 10^9/L, range = (140 - 450)], high protein [3+, range = NEGATIVE], high alanine aminotransferase [82 U/L, range = (4 - 41)], high alkaline phosphatase [161 U/L, range = (40 - 129)], high aspartate aminotransferase [83 U/L, range = (4 - 37)], and high glucose [13.4 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 852), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [109 umol/L, range = (62 - 106), BL =normal], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and high occult blood [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 922) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG ADENOCARCINOMA METASTATIC [LUNG ADENOCARCINOMA METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 217) the subject experienced lung adenocarcinoma metastatic (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 174 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung adenocarcinoma metastatic and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, beta blocker, prasugrel, and unknown.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.65 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 217) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 632) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 462 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], low creatine kinase [22 IU/L, range = (24 - 170)], high glucose [6.8 mmol/L, range = (4.1 - 5.9)], low hemoglobin [113 g/L, range = (116 - 162)], low magnesium [0.55 mmol/L, range = (0.65 - 1.05)], high protein [1+, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.14 - 7.14), BL =normal], high creatinine [130 umol/L, range = (44 - 80), BL =normal], normal hemoglobin [122 g/L, range = (116 - 162), BL =low], normal specific gravity [1.03, range = (1 - 1.04), BL =high], and high urate [387 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 632) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SEPSIS [SEPSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 344) the subject experienced sepsis (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 318 days after the last dose of any study medication.

Concomitant medications taken at the onset of the sepsis and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low magnesium [0.6 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 344) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 418) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 234 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.12 mg/L, range = (0 - 3)], high blood urea nitrogen [9.28 mmol/L, range = (2.14 - 7.14)], high glucose [8.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], high protein [1+, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 156), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high glucose [trace, range = NEGATIVE, BL =normal], and normal leukocytes [0-3 /HPF, range = 0-3, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 418) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Non-Cardiovascular Procedure Or Surgery)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 860) the subject experienced obesity [adipositas per magna] (Grade 3) and underwent gastric banding surgery. On PPD , the subject developed post-operative bleeding and renal failure. On PPD (Day 941) the subject died due to the event. The event was considered serious for the following reasons: results in death. The event occurred 100 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, cefuroxim, ciprofloxacin, glycemic control medication, insulin, and sultamicillin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.56 mg/L, range = (0 - 3)], high alkaline phosphatase [156 U/L, range = (40 - 129)], high creatine kinase [303 IU/L, range = (24 - 250)], high glucose [3+, range = NEGATIVE], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [203 IU/L, range = (24 - 250), BL =high], and normal urate [399 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 941) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Endocarditis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 890) the subject experienced death. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and cefuroxim.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.14 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high creatinine [112 umol/L, range = (62 - 106)], high glucose [7 mmol/L, range = (4.6 - 6.4)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [33 g/L, range = (35 - 52), BL =normal], normal creatinine [96 umol/L, range = (62 - 106), BL =high], low erythrocytes [3.9 10^12/L, range = (4 - 5.8), BL =normal], normal glucose [6.3 mmol/L, range = (4.6 - 6.4), BL =high], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [107 g/L, range = (130 - 177), BL =normal], high leukocytes [13.6 10^9/L, range = (4.1 - 12.3), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 890) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 490) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 67 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [181 U/L, range = (40 - 129)], high glucose [29.6 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline:** low glucose [2.6 mmol/L, range = (4.6 - 6.4), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], high protein [1+, range = NEGATIVE, BL =normal], and normal specific gravity [1.03, range = (1 - 1.04), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 490) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): RENAL FAILURE [RENAL FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 409) the subject experienced laryngeal cancer metastatic [laryngeal carcinoma metastatic] (Grade 3) and on PPD (Day 494) the subject experienced renal failure (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 157 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the renal failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high occult blood [trace, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], low hemoglobin [129 g/L, range = (130 - 175), BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 494) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): EMBOLISM [EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (PE)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 621) the subject experienced embolism (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 468 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the embolism and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.95 mg/L, range = (0 - 3)], low hemoglobin [122 g/L, range = (130 - 177)], high alanine aminotransferase [87 U/L, range = (4 - 41)], high alkaline phosphatase [500 U/L, range = (40 - 129)], high aspartate aminotransferase [73 U/L, range = (4 - 37)], high bilirubin [1+, range = NEGATIVE], low glucose [4.2 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [297 U/L, range = (5 - 250)], high protein [trace, range = NEGATIVE], and high sodium [150 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], normal glucose [6.3 mmol/L, range = (4.6 - 6.4), BL =low], normal hemoglobin [130 g/L, range = (130 - 177), BL =low], low platelets [105 10^9/L, range = (140 - 450), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and normal sodium [145 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 621) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH OF UNKNOWN CAUSE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 831) the subject experienced death [death of unknown cause] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, cefpodoxim, ceftriaxon, clarithromycin, and unacid.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 678), the subject had the following on-study laboratory test results with results different than baseline: low blood urea nitrogen [2.64 mmol/L, range = (2.86 - 8.21), BL =normal], high calcium [2.67 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.68 mmol/L, range = (2.1 - 2.58), BL =normal], high glucose [6.7 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [124 g/L, range = (130 - 175), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], high leukocytes [13.4 10^9/L, range = (4.1 - 12.3), BL =normal], high platelets [483 10^9/L, range = (140 - 450), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 831) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [STEMI]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 250) the subject experienced acute myocardial infarction [stemi] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [130 U/L, range = (40 - 129), BL =normal], normal bilirubin [negative, range = NEGATIVE, BL =high], high calcium [2.73 mmol/L, range = (2.1 - 2.58), BL =normal], and high calcium corrected [2.73 mmol/L, range = (2.1 - 2.58), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 250) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): EMBOLISM [EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Pulmonary Embolism)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 29) the subject experienced embolism (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the embolism and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [43 U/L, range = (4 - 41)], high CRP [7.75 mg/L, range = (0 - 3)], high glucose [6.5 mmol/L, range = (4.1 - 5.9)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 29) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC DEATH [CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 417) the subject experienced cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 81 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac death and up to 30 days prior to event onset included: amoxicomp 500/ 125, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.15 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high creatinine [131 umol/L, range = (62 - 106)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** low glucose [3.4 mmol/L, range = (4.1 - 5.9), BL =normal], and high leukocytes [12.6 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 417) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH OF UNKNOWN CAUSE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 182) the subject experienced sudden death [sudden death of unknown cause] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, glycemic control medication, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: low alkaline phosphatase [39 U/L, range = (40 - 129)], high glucose [8.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 174), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [44 U/L, range = (4 - 41), BL =normal], normal alkaline phosphatase [49 U/L, range = (40 - 129), BL =low], high bilirubin [1+, range = NEGATIVE, BL =normal], and high glucose [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 182) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): COLON CANCER [COLON CARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 679) the subject experienced colon cancer [colon carcinoma] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. On PPD, the subject experienced cardiac decompensation with reduction of his general condition and on the same day was admitted to the hospital. He was diagnosed with decompensated heart insufficiency and hepatorenal syndrome. He developed ureteral stricture and was found to have colon cancer. On PPD, the subject died due to colon cancer and hepatorenal syndrome. The event occurred 90 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the colon cancer and up to 30 days prior to event onset included: atorvastatin, and unacid.

The subject had the following abnormal laboratory test results at baseline: high glucose [8.7 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [120 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [130 U/L, range = (40 - 129), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], low leukocytes [3.5 10^9/L, range = (4.1 - 12.3), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and low protein [59 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 679) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GLIOBLASTOMA MULTIFORME [GLIOBLASTOMA MULTIFORME]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On P PPD (day 741) the subject was diagnosed with glioblastoma. On PPD , the subject's condition suddenly worsened with increase disorientation and change of personality. The subject was hospitalized and tumor bleeding was detected. Tumor bleeding increased despite of invasive decompression procedures. On PPD (Day 758) the subject died from glioblastoma multiforme. The event was considered serious for the following reasons: results in death. The event occurred 85 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the glioblastoma multiforme and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.17 mg/L, range = (0 - 3)], low hemoglobin [125 g/L, range = (130 - 177)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [0.24 mg/L, range = (0 - 3), BL =high], normal hemoglobin [130 g/L, range = (130 - 177), BL =low], and normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 758) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 395) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 226 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, ezetimibe, and unacid.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high creatinine [109 umol/L, range = (62 - 106)], high glucose [10.1 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [123 g/L, range = (130 - 175)], and high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [4 10^12/L, range = (4.1 - 5.9), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 395) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 297) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 43 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high creatinine [113 umol/L, range = (62 - 106)], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [32.5 10^9/L, range = (4.1 - 12.3)], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], and low hemoglobin [129 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 297) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [HYPERCAPNIC RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1055) the subject experienced respiratory failure [hypercapnic respiratory failure] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 984 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: amphomoronal, ampicillin, atorvastatin, ciprofloxacin, clarithromycin, sulbactam, and tazobac.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.71 mg/L, range = (0 - 3)], high glucose [6.5 mmol/L, range = (4.6 - 6.4)], and high urate [399 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1055) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): NEOPLASM MALIGNANT [CANCER (NOS)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD , the subject developed lumboischialgia. Approximately three months later on PPD , the subject was hospitalized due to worsening of lumboischalgia. During hospitalization he was found to have metastases to bone and liver. No primary cancer was identified but prostate cancer was suspected. Treatment included palliative chemotherapy and radiotherapy. On PPD (Day 675) the subject experienced acute kidney injury [acute renal failure] (Grade 3). On PPD (Day 707) the subject experienced sepsis (Grade 3) and on PPD (Day 741) the subject experienced gallbladder perforation (Grade 3). On PPD (Day 794) the subject died from neoplasm malignant [cancer (nos)] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 135 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the neoplasm malignant and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.82 mg/L, range = (0 - 3)], high glucose [8.2 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], and high urate [553 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [49 U/L, range = (4 - 37), BL =normal], normal potassium [4.6 mmol/L, range = (3.3 - 5.1), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 794) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 810) the subject experienced death. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and other medically important serious event. The event occurred 53 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: cefuroxim, cefuroxime, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.71 mg/L, range = (0 - 3)], high blood urea nitrogen [12.5 mmol/L, range = (2.86 - 8.21)], high glucose [6.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high protein [2+, range = NEGATIVE], low sodium [130 mmol/L, range = (135 - 147)], and high urate [476 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [128 umol/L, range = (62 - 106), BL =normal], normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high], and normal sodium [144 mmol/L, range = (135 - 147), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 810) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1051) the subject experienced myocardial infarction (Grade 4) and on PPD (Day 1053) the subject died. The event was considered serious for the following reasons: results in death. The event occurred 44 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], high glucose [14.3 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [119 g/L, range = (130 - 177)], and high potassium [5.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21), BL =normal], normal glucose [6.4 mmol/L, range = (4.6 - 6.4), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], normal platelets [255 10^9/L, range = (140 - 450), BL = missing], high protein [2+, range = NEGATIVE, BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1053) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 816) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], and high urate [476 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 672), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 816) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 280) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 27 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [562 IU/L, range = (24 - 250)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 175), the subject had the following on-study laboratory test results with results different than baseline:** low alkaline phosphatase [39 U/L, range = (40 - 129), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 280) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 245) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 71 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [49 U/L, range = (4 - 41)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], and high urate [446 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [13 U/L, range = (4 - 41), BL =high], high creatinine [118 umol/L, range = (62 - 106), BL =normal], and normal erythrocytes [4 10^12/L, range = (4 - 5.8), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 245) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): NON-SMALL CELL LUNG CANCER STAGE III [LUNG CANCER NON-SMALL CELL STAGE III]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1030) the subject experienced non-small cell lung cancer stage iii [lung cancer non-small cell stage iii] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 99 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the non-small cell lung cancer stage iii and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high leukocytes [31-50 /HPF, range = 0-3], and high urate [535 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 850), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [7.3 mmol/L, range = (4.6 - 6.4), BL =normal], normal urate [410 umol/L, range = (202 - 416), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 1030) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 972) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.2 mg/L, range = (0 - 3)], high aspartate aminotransferase [52 U/L, range = (4 - 37)], and low erythrocytes [3.9 10^12/L, range = (4 - 5.8)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 847), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], high bilirubin [1+, range = NEGATIVE, BL =normal], low hematocrit [0.32 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [99 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [347 U/L, range = (5 - 250), BL =normal], high platelets [535 10^9/L, range = (140 - 450), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 972) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 460) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 30 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [10.35 mmol/L, range = (2.14 - 7.14)], high glucose [10.2 mmol/L, range = (4.1 - 5.9)], high glucose [2+, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high potassium [5.6 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], and high urate [506 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 347), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.43 mmol/L, range = (2.14 - 7.14), BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 460) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 799) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 35 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.36 mg/L, range = (0 - 3)], high glucose [8.9 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high leukocytes [13.1 10^9/L, range = (4.1 - 12.3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 688), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [43 U/L, range = (4 - 37), BL =normal], high bilirubin [26 umol/L, range = (3 - 21), BL =normal], and normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 799) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 502) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 72 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.6 mg/L, range = (0 - 3)], high erythrocytes [6-8 /HPF, range = 0-5], high calcium [2.63 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58)], high glucose [6.4 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high protein [86 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [0.55 mg/L, range = (0 - 3), BL =high], normal calcium [2.5 mmol/L, range = (2.1 - 2.58), BL =high], normal calcium corrected [2.5 mmol/L, range = (2.1 - 2.58), BL =high], and normal glucose [4.7 mmol/L, range = (4.1 - 5.9), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 502) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 402) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 401 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [tntc /HPF, range = 0-12], high thyrotropin [4.83 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [115 U/L, range = (35 - 104)], high glucose [24 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high protein [1+, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [94 U/L, range = (35 - 104), BL =high], high CRP [19.3 mg/L, range = (0 - 3), BL =normal], high creatinine [83 umol/L, range = (44 - 80), BL =normal], low hemoglobin [107 g/L, range = (116 - 162), BL =normal], and high urate [357 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 402) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 7) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and ticagrelor.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high CRP [4.49 mg/L, range = (0 - 3)], high calcium [2.65 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 7) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC MONITORING [CARDIORESPIRATORY MONITORING]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1051) the subject experienced cardiac monitoring [cardiorespiratory monitoring] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 894 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac monitoring and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14)], low erythrocytes [4 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [120 g/L, range = (130 - 175)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 87), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.5 mmol/L, range = (2.86 - 8.21), BL =high], normal erythrocytes [4.2 10^12/L, range = (4.1 - 5.9), BL =low], and high potassium [5.5 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1051) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 43) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be related to IP and related to statin. The event ended on PPD (Day 43) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 449) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and other medically important serious event. The event occurred 448 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high calcium [2.6 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55)], high creatinine [141 umol/L, range = (62 - 106)], low glucose [2.9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 449) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CONFUSIONAL STATE [CONFUSION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 13) the subject experienced non-small cell lung cancer [non small cell lung cancer] (Grade 4) with subsequent bone metasteses. In PPD the subject was confused and found to have increasing lung mass; he was placed in hospice. PPD (Day 559) the subject experienced confusional state [confusion] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 85 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the confusional state and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.1 mg/L, range = (0 - 3)], low hemoglobin [126 g/L, range = (130 - 177)], low platelets [117 10^9/L, range = (140 - 450)], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [130 umol/L, range = (62 - 106), BL =normal], low erythrocytes [3.9 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], high lactate dehydrogenase [427 U/L, range = (5 - 250), BL =normal], and normal platelets [143 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 559) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 527) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 274 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [24.44 mg/L, range = (0 - 3)], and high bilirubin [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [26 umol/L, range = (3 - 21), BL =normal], high glucose [3+, range = NEGATIVE, BL =normal], and high urate [422 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 527) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GASTRIC CANCER [GASTRIC CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 287) the subject experienced gastric cancer (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 67 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastric cancer and up to 30 days prior to event onset included: rosuvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline: high alanine aminotransferase [48 U/L, range = (4 - 41), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], and high glucose [6.6 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 287) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION ACUTE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 272) the subject experienced acute myocardial infarction [myocardial infarction acute] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, beta blocker, glycemic control medication, rosuvastatin, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [22 umol/L, range = (3 - 21)], low creatinine [57 umol/L, range = (62 - 106)], high glucose [1+, range = NEGATIVE], and low hemoglobin [123 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** low calcium [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], high creatine kinase [280 IU/L, range = (20 - 203), BL =normal], normal creatinine [92 umol/L, range = (62 - 106), BL =low], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and normal hemoglobin [137 g/L, range = (130 - 177), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 272) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 525) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 23 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, beta blocker, clopidogrel, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.02 mg/L, range = (0 - 3)], high aspartate aminotransferase [46 U/L, range = (4 - 37)], high glucose [3+, range = NEGATIVE], and high leukocytes [12.4 10^9/L, range = (4.1 - 12.3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 502), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [16 U/L, range = (4 - 37), BL =high], low calcium [2.1 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.13 mmol/L, range = (2.2 - 2.55), BL =normal], low creatinine [56 umol/L, range = (62 - 106), BL =normal], low hematocrit [0.3 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [87 g/L, range = (130 - 177), BL =normal], normal leukocytes [7.8 10^9/L, range = (4.1 - 12.3), BL =high], and low protein [58 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 525) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 525) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.3 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], and high glucose [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 504), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], low hemoglobin [127 g/L, range = (130 - 177), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 525) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): HAEMORRHAGIC TRANSFORMATION STROKE [HAEMORRHAGIC TRANSFORMATION DUE TO ACUTE STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 800) the subject experienced haemorrhagic transformation stroke [haemorrhagic transformation due to acute stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 546 days after the last dose of any study medication.

Concomitant medications taken at the onset of the haemorrhagic transformation stroke and up to 30 days prior to event onset included: atorvastatin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low creatinine [61 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [126 g/L, range = (130 - 175)], and low platelets [139 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 503), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [73 umol/L, range = (62 - 106), BL =low], high glucose [3+, range = NEGATIVE, BL =normal], and low leukocytes [3.7 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 800) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 400) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.43 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [10.71 mmol/L, range = (2.14 - 7.14)], high creatinine [137 umol/L, range = (62 - 106)], high glucose [9 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [122 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], and high urate [529 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.14 mmol/L, range = (2.14 - 7.14), BL =high], normal creatinine [103 umol/L, range = (62 - 106), BL =high], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], low magnesium [0.6 mmol/L, range = (0.65 - 1.05), BL =normal], normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 400) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 926) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 183 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: 1x2 g ceftriaxon iv., and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.97 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high creatinine [123 umol/L, range = (62 - 106)], high erythrocytes [6-8 /HPF, range = 0-5], high occult blood [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [278 U/L, range = (40 - 129), BL =normal], normal bilirubin [negative, range = NEGATIVE, BL =high], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [117 g/L, range = (130 - 175), BL =normal], high lactate dehydrogenase [272 U/L, range = (5 - 250), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], high platelets [454 10^9/L, range = (140 - 450), BL =normal], and high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 926) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 239) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.5 mg/L, range = (0 - 3)], and high alkaline phosphatase [140 U/L, range = (35 - 104)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 239) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SEPSIS [SEPTICEMIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 297) the subject experienced sepsis [septicemia] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 23 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sepsis and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.25 mg/L, range = (0 - 3)], low HbA1c [<0.041 fraction of 1], and low urate [131 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 166), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [7.9 mmol/L, range = (4.6 - 6.4), BL =normal], high leukocytes [13-30 /HPF, range = 0-12, BL =normal], and normal urate [178 umol/L, range = (143 - 339), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 297) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 605) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.4 mmol/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.8 mmol/L, range = (4.1 - 5.9), BL =high], high occult blood [trace, range = NEGATIVE, BL =normal], and high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 605) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BRAIN NEOPLASM [BRAIN TUMOR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 500) the subject experienced haemangiopericytoma [anaplastic hemangiopericytoma] (Grade 4) and on PPD (Day 691) the subject die due to brain neoplasm [brain tumor] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 256 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the brain neoplasm and up to 30 days prior to event onset included: angiotensin receptor blocker, atorvastatin, beta blocker, clopidogrel, and fraxiparin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.4 mmol/L, range = (4.1 - 5.9)], high occult blood [trace, range = NEGATIVE], high protein [1+, range = NEGATIVE], and high urate [363 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 668), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [31 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [164 U/L, range = (35 - 104), BL =normal], high calcium corrected [2.73 mmol/L, range = (2.1 - 2.58), BL =normal], low creatine kinase [10 IU/L, range = (24 - 170), BL =normal], low erythrocytes [2.5 10^12/L, range = (3.8 - 5.5), BL =normal], low hematocrit [0.21 fraction of 1, range = (0.35 - 0.47), BL =normal], low hemoglobin [65 g/L, range = (116 - 162), BL =normal], high lactate dehydrogenase [434 U/L, range = (5 - 250), BL =normal], high leukocytes [16.7 10^9/L, range = (4.1 - 12.3), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], high platelets [733 10^9/L, range = (140 - 450), BL =normal], and normal urate [333 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 691) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): NEOPLASM MALIGNANT [CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 591) the subject experienced neoplasm malignant [cancer] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 86 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the neoplasm malignant and up to 30 days prior to event onset included: analgesic or antipyretic agent, angiotensin receptor blocker, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.51 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [115 umol/L, range = (62 - 106)], high glucose [16.9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high potassium [5.7 mmol/L, range = (3.3 - 5.1)], and high urate [446 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [2+, range = NEGATIVE, BL =normal], normal blood urea nitrogen [8.18 mmol/L, range = (2.86 - 8.21), BL =high], high calcium [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], normal creatinine [87 umol/L, range = (62 - 106), BL =high], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [trace, range = NEGATIVE, BL =normal], high hematocrit [0.52 fraction of 1, range = (0.37 - 0.5), BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 591) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 66) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [107 umol/L, range = (62 - 106)], high leukocytes [4-12 /HPF, range = 0-3], low platelets [128 10^9/L, range = (140 - 450)], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 66) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 460) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acenocoumerol, acetylsalicylic acid, aldosterone antagonist, augmentin, beta blocker, cefazolin, ceftibuten, cefuroxim (zinnat), curam duo (amoxicillin/clavulanic acid), and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.07 mg/L, range = (0 - 3)], low thyrotropin [0.07 mU/L, range = (0.55 - 4.78)], high bilirubin [22 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high direct bilirubin [10 umol/L, range = (0 - 5)], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [2.45 mg/L, range = (0 - 3), BL =high], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 460) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 470) the subject experienced acute myocardial infarction. The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 49 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, glycemic control medication, insulin, rosuvastatin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.57 mg/L, range = (0 - 3)], high glucose [9 mmol/L, range = (4.1 - 5.9)], high glucose [1+, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high potassium [5.4 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [2.74 mg/L, range = (0 - 3), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 470) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 6) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, and beta blocker.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 6) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): HEPATIC CANCER [HEPATIC ADENOCARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 406) the subject experienced hepatic cancer [hepatic adenocarcinoma] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 63 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the hepatic cancer and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], and high creatinine [133 umol/L, range = (44 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 343), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [296 U/L, range = (35 - 104), BL =normal], high aspartate aminotransferase [44 U/L, range = (4 - 31), BL =normal], normal blood urea nitrogen [7.89 mmol/L, range = (2.86 - 8.21), BL =high], low hemoglobin [107 g/L, range = (110 - 161), BL =normal], high lactate dehydrogenase [633 U/L, range = (5 - 250), BL =normal], and high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 406) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 348) the subject experienced pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 263 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: amikin (amikacine), atorvastatin, fortum (cefazidine), mycosyst (fluconazole), sumetrolim (sulfamethoxazole and trimethoprim), telviran (acyclovir), and tienam (karbapenem).

The subject had the following abnormal laboratory test results at baseline: high CRP [27.53 mg/L, range = (0 - 3)], high alkaline phosphatase [208 U/L, range = (40 - 129)], high bilirubin [1+, range = NEGATIVE], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], high erythrocytes [9-14 /HPF, range = 0-5], low hemoglobin [129 g/L, range = (130 - 177)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high occult blood [2+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [114 umol/L, range = (62 - 106), BL =normal], low hematocrit [0.26 fraction of 1, range = (0.37 - 0.5), BL =normal], high lactate dehydrogenase [334 U/L, range = (5 - 250), BL =normal], and low platelets [112 10^9/L, range = (140 - 450), BL =normal].

Action taken with statin was dose not changed. The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 348) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 858) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 857 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [397 IU/L, range = (24 - 250)], and high potassium [5.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 833), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [56 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [45 U/L, range = (4 - 37), BL =normal], and normal potassium [5.1 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 858) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ISCHAEMIC STROKE [ISCHAEMIC STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 251) the subject experienced ischaemic stroke (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 2 days after the last dose of any study medication.

Concomitant medications taken at the onset of the ischaemic stroke and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.84 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high calcium [2.65 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.65 mmol/L, range = (2.1 - 2.58)], high creatinine [83 umol/L, range = (44 - 80)], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.5)], high lactate dehydrogenase [318 U/L, range = (5 - 250)], and high protein [81 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.45 mmol/L, range = (2.1 - 2.58), BL =high], normal calcium corrected [2.45 mmol/L, range = (2.1 - 2.58), BL =high], low hemoglobin [114 g/L, range = (116 - 162), BL =normal], and normal protein [74 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 251) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1062) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 1019 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.21 mg/L, range = (0 - 3)], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.4)], high glucose [20.1 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 64), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [1.78 mg/L, range = (0 - 3), BL =high], and normal glucose [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1062) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 578) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 577 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ezetimibe, prixoter, simvastatin, and vytorin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.11 mg/L, range = (0 - 3)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], high glucose [7.2 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [118 g/L, range = (130 - 177)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 507), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.2 mmol/L, range = (4.6 - 6.4), BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], high urate [452 umol/L, range = (202 - 416), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 578) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CIRCULATORY COLLAPSE [FAILURE CIRCULATORY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 838) the subject experienced cardiac failure congestive [heart failure, congestive] (Grade 4) and on PPD (Day 859) the subject experienced circulatory collapse [failure circulatory] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 102 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the circulatory collapse and up to 30 days prior to event onset included: ezetimibe, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.51 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 667), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [134 umol/L, range = (44 - 80), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 859) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 185) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 100 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [37.89 mg/L, range = (0 - 3)], high creatinine [108 umol/L, range = (62 - 106)], high erythrocytes [tntc /HPF, range = 0-5], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], high leukocytes [tntc /HPF, range = 0-3], high occult blood [3+, range = NEGATIVE], high protein [2+, range = NEGATIVE], and low urate [196 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.8 mmol/L, range = (4.6 - 6.4), BL =high], and normal urate [220 umol/L, range = (202 - 416), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 185) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [INFARCT MYOCARDIAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 139) the subject experienced myocardial infarction [infarct myocardial] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 54 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [38.69 mg/L, range = (0 - 3)], high erythrocytes [15-30 /HPF, range = 0-5], high occult blood [3+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.2 mmol/L, range = (4.1 - 5.9), BL =normal], and low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 139) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BREAST CANCER [EARLY STAGE BREAST CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 388) the subject experienced breast cancer [early stage breast cancer] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 345 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.67 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [34 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high creatinine [133 umol/L, range = (44 - 80)], high glucose [10.8 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 335), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.78 mmol/L, range = (2.86 - 8.21), BL =high], normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [523 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 388) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 895) the subject experienced sudden cardiac death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: fenofibrate, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14)], high glucose [10 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 845), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [24 umol/L, range = (3 - 21), BL =normal], high creatinine [127 umol/L, range = (62 - 106), BL =normal], high direct bilirubin [13 umol/L, range = (0 - 5), BL =normal], and high lactate dehydrogenase [252 U/L, range = (5 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 895) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): METASTASES TO LUNG [METASTASES TO LUNG]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 194) the subject experienced metastases to lung (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 27 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the metastases to lung and up to 30 days prior to event onset included: angiotensin receptor blocker, beta blocker, ezetimibe, glycemic control medication, insulin, rosuvastatin, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high CRP [27.81 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high creatinine [134 umol/L, range = (62 - 106)], high glucose [9.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [27 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [251 U/L, range = (40 - 129), BL =normal], normal blood urea nitrogen [5.71 mmol/L, range = (2.86 - 8.21), BL =high], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], normal creatinine [72 umol/L, range = (62 - 106), BL =high], low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.33 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [104 g/L, range = (130 - 177), BL =normal], and low protein [55 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 194) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 984) the subject experienced sudden death [sudden death, cause unknown]. The event was considered serious for the following reasons: results in death. The event occurred 897 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ciprofloxacin, and zinnat 500mg.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.46 mU/L, range = (0.55 - 4.78)], high glucose [11.5 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high erythrocytes [9-14 /HPF, range = 0-5, BL =normal], and high occult blood [3+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 984) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPTIC SHOCK [SHOCK SEPTIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On P PPD the subject experienced pneumonia, and on PPD he experienced Enterobacter bacteremia, septic shock, renal failure, and multiorgan failure. On PPD (Day 702) the subject died from septic shock. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 30 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the septic shock and up to 30 days prior to event onset included: ciprofloxacin, ciprofloxacin 500 mg, ezetimibe, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.1 mU/L, range = (0.55 - 4.78)], high protein [trace, range = NEGATIVE], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 672), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [128 umol/L, range = (62 - 106), BL =normal], low hemoglobin [123 g/L, range = (130 - 177), BL =normal], high leukocytes [31-50 /HPF, range = 0-3, BL =normal], high occult blood [1+, range = NEGATIVE, BL =normal], and normal urate [309 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 702) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 749) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 76 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.09 mg/L, range = (0 - 3)], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], and high urate [345 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [13 10^9/L, range = (4.1 - 12.3), BL =normal], and normal leukocytes [0-3 /HPF, range = 0-12, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 749) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): HEPATIC FAILURE [HEPATIC FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Hepatobiliary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 576) the subject experienced hepatic failure. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. On P PPD , the subject experienced increasing decreased urine output, leg edema, abdomen tightness, and dyspnea. He was hospitalized and diagnosed with subacute hepatic failure, possibly caused by cholangio-hepatitis. No acute viral hepatitis was noted. On PPD , the subject died due to subacute hepatic failure with probably chronic alcholoism in the background complemented by non-viral hepatitis. The investigator reported that other comorbidities that had role in this event were type 2 diabetes, aortic stenosis and ischemic heart disease. The event occurred 72 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the hepatic failure and up to 30 days prior to event onset included: ciprofloxacin, metronidazole, and rosuvastatin.

Date	Visit	Relative Day	AST range 4-37 U/L	ALT range 4-41 U/L	ALP range 40-129 U/L	T. Bili range 3-21 umol/L
PPD	DAY 1	1	28	30	89	10
	WEEK 12	86	26	33	79	15
	WEEK 24	176	146	326	125	26
	WEEK 48	344	28	20	98	21
	WEEK 72	504	21	9	99	29

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 576) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [ASYSTOLIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 806) the subject experienced cardiac arrest [asystolia] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.41 mg/L, range = (0 - 3)], high blood urea nitrogen [8.93 mmol/L, range = (2.14 - 7.14)], high glucose [10.9 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 676), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.43 mmol/L, range = (2.86 - 8.21), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [122 g/L, range = (130 - 175), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 806) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DROWNING [DROWNING]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 740) the subject experienced drowning (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the drowning and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.75 mg/L, range = (0 - 3)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high protein [3+, range = NEGATIVE], and high urate [547 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 671), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [7.9 mmol/L, range = (4.6 - 6.4), BL =normal], normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high], and normal urate [357 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 740) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GASTROINTESTINAL TOXICITY [TOXIC GASTROENTERITIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 141) the subject experienced gastrointestinal toxicity [toxic gastroenteritis] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 140 days after the first dose of any study medication.

Concomitant medications taken at the onset of the gastrointestinal toxicity and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glucose [4.2 mmol/L, range = (4.6 - 6.4)], high leukocytes [12.4 10^9/L, range = (4.1 - 12.3)], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 87), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.1 mmol/L, range = (4.6 - 6.4), BL =low], normal leukocytes [9.8 10^9/L, range = (4.1 - 12.3), BL =high], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 141) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 308) the subject experienced cardiac failure [heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high occult blood [trace, range = NEGATIVE], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 239), the subject had the following on-study laboratory test results with results different than baseline:** normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 308) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 339) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 114 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: curam duo, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low blood urea nitrogen [2.5 mmol/L, range = (2.86 - 8.21)], high CRP [8.24 mg/L, range = (0 - 3)], low creatinine [52 umol/L, range = (62 - 106)], low glucose [3.9 mmol/L, range = (4.6 - 6.4)], and high sodium [150 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 180), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [64 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [96 U/L, range = (4 - 37), BL =normal], normal creatinine [63 umol/L, range = (62 - 106), BL =low], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], normal glucose [5.1 mmol/L, range = (4.6 - 6.4), BL =low], and normal sodium [145 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 339) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): HAEMORRHAGIC STROKE [HAEMORRHAGIC STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 74) the subject experienced haemorrhagic stroke (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 19 days after the last dose of any study medication.

Concomitant medications taken at the onset of the haemorrhagic stroke and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [62 U/L, range = (4 - 41)], high aspartate aminotransferase [62 U/L, range = (4 - 37)], high bilirubin [1+, range = NEGATIVE], high creatine kinase [295 IU/L, range = (24 - 250)], high glucose [9.2 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 74) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 433) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 113 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acenocoumerol, atorvastatin, beta blocker, clopidogrel, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.99 mg/L, range = (0 - 3)], low glucose [3.8 mmol/L, range = (4.6 - 6.4)], low hemoglobin [126 g/L, range = (130 - 177)], high leukocytes [4-12 /HPF, range = 0-3], and low magnesium [0.6 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [6.2 mmol/L, range = (4.6 - 6.4), BL =low], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], and normal magnesium [0.7 mmol/L, range = (0.65 - 1.05), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 433) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 407) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death, and other medically important serious event. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: ezetimibe, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.04 mg/L, range = (0 - 3)], high creatinine [84 umol/L, range = (44 - 80)], high glucose [12.2 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [31-50 /HPF, range = 0-12], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [1.89 mg/L, range = (0 - 3), BL =high], normal creatinine [80 umol/L, range = (44 - 80), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], normal leukocytes [4-12 /HPF, range = 0-12, BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 407) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 556) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 48 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low platelets [139 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 508), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high creatine kinase [332 IU/L, range = (24 - 250), BL =normal], low erythrocytes [3.8 10^12/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [118 g/L, range = (130 - 175), BL =normal], high lactate dehydrogenase [264 U/L, range = (5 - 250), BL =normal], normal platelets [170 10^9/L, range = (140 - 450), BL =low], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 556) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): NEOPLASM MALIGNANT [CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 532) the subject experienced gastric cancer [stomach cancer] (Grade 4) and PPD (Day 614) the subject died due to neoplasm malignant [cancer] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 39 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the neoplasm malignant and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, antidepressants, beta blocker, ciprobay, fraxiparin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.66 mg/L, range = (0 - 3)], high erythrocytes [6-8 /HPF, range = 0-5], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [47 U/L, range = (4 - 41), BL =normal], high alkaline phosphatase [274 U/L, range = (40 - 129), BL =normal], high aspartate aminotransferase [43 U/L, range = (4 - 37), BL =normal], high bilirubin [2+, range = NEGATIVE, BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 614) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 159) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 114 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.76 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [82 umol/L, range = (44 - 80)], and low glucose [4.4 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [48 U/L, range = (4 - 31), BL =normal], and normal blood urea nitrogen [6.78 mmol/L, range = (2.86 - 8.21), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 159) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 433) the subject experienced acute myocardial infarction. The event was considered serious for the following reasons: results in death. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.29 mg/L, range = (0 - 3)], and low platelets [127 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [68 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [38 U/L, range = (4 - 37), BL =normal], normal CRP [1.29 mg/L, range = (0 - 3), BL =high], normal platelets [141 10^9/L, range = (140 - 450), BL =low], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 433) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE CHRONIC [HEART FAILURE NYHA CLASS IV]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 259) the subject experienced cardiac failure chronic [heart failure nyha class iv] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure chronic and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, antidepressants, atorvastatin, beta blocker, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [12.14 mmol/L, range = (2.86 - 8.21)], high CRP [6.37 mg/L, range = (0 - 3)], high creatinine [113 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [117 g/L, range = (130 - 177)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [55 U/L, range = (4 - 41), BL =normal], low calcium [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and high urate [523 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 259) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 667) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high CRP [4.43 mg/L, range = (0 - 3)], high glucose [6 mmol/L, range = (4.1 - 5.9)], high protein [2+, range = NEGATIVE], and high protein [82 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 507), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14), BL =normal], high creatinine [118 umol/L, range = (62 - 106), BL =normal], normal glucose [5.5 mmol/L, range = (4.6 - 6.4), BL =high], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], normal protein [76 g/L, range = (60 - 80), BL =high], high urate [571 umol/L, range = (202 - 416), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 667) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): COMPLETED SUICIDE [SUICIDE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Suicide)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 354) the subject experienced completed suicide [suicide] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 22 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the completed suicide and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, antidepressants, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.66 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [45 mL/min/1.73m2, range = (60 - 9999)], high glucose [6.5 mmol/L, range = (4.1 - 5.9)], high leukocytes [13-30 /HPF, range = 0-12], and high occult blood [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 332), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.93 mmol/L, range = (2.14 - 7.14), BL =normal], normal CRP [3 mg/L, range = (0 - 3), BL =high], high erythrocytes [5.6 10^12/L, range = (3.8 - 5.5), BL =normal], and high hematocrit [0.49 fraction of 1, range = (0.35 - 0.47), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 354) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 661) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 71 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], high creatine kinase [365 IU/L, range = (24 - 250)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high sodium [150 mmol/L, range = (135 - 147)], low urate [137 umol/L, range = (202 - 416)], high glucose [2+, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], and high leukocytes [13-30 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 507), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [56 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [43 U/L, range = (4 - 37), BL =normal], high bilirubin [1+, range = NEGATIVE, BL =normal], high lactate dehydrogenase [313 U/L, range = (5 - 250), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high], high protein [1+, range = NEGATIVE, BL =normal], normal sodium [144 mmol/L, range = (135 - 147), BL =high], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 661) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 207) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 206 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [97.42 mg/L, range = (0 - 3)], high creatine kinase [263 IU/L, range = (24 - 250)], low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9)], high glucose [9 mmol/L, range = (4.1 - 5.9)], and high potassium [5.4 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal erythrocytes [4.3 10^12/L, range = (4.1 - 5.9), BL =low], normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 207) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 458) the subject experienced cardiac failure [heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 37 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.83 mg/L, range = (0 - 3)], high erythrocytes [15-30 /HPF, range = 0-5], high leukocytes [13-30 /HPF, range = 0-3], high occult blood [3+, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 365), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [24 g/L, range = (35 - 52), BL =normal], high blood urea nitrogen [9.82 mmol/L, range = (2.86 - 8.21), BL =normal], low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], high glucose [9 mmol/L, range = (4.6 - 6.4), BL =normal], low hematocrit [0.32 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [100 g/L, range = (130 - 177), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and low protein [59 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 458) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 260) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 92 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high glucose [12.8 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 260) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RENAL CANCER METASTATIC [RENAL CANCER METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 468) the subject experienced renal cancer metastatic (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 48 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the renal cancer metastatic and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.83 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [6.19 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [12.85 mmol/L, range = (2.86 - 8.21)], high creatinine [115 umol/L, range = (62 - 106)], and high potassium [5.6 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal blood urea nitrogen [6.71 mmol/L, range = (2.86 - 8.21), BL =high], high glucose [9.2 mmol/L, range = (4.6 - 6.4), BL =normal], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [107 g/L, range = (130 - 177), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 468) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 606) the subject experienced lung neoplasm malignant [lung cancer]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 115 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [51 U/L, range = (4 - 41), BL =normal], high glucose [12.9 mmol/L, range = (4.6 - 6.4), BL =normal], and high glucose [3+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 606) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [DEATH- HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 168) the subject experienced cardiac failure [death- heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 111 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: atorvastatin, and ciprofloxacin hydrochloride.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.3 mg/L, range = (0 - 3)], low hemoglobin [125 g/L, range = (130 - 177)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 88), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [46 U/L, range = (4 - 41), BL =normal], low albumin [32 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [150 U/L, range = (40 - 129), BL =normal], high aspartate aminotransferase [43 U/L, range = (4 - 37), BL =normal], high bilirubin [67 umol/L, range = (3 - 21), BL =normal], high creatine kinase [240 IU/L, range = (20 - 203), BL =normal], high creatinine [114 umol/L, range = (62 - 106), BL =normal], high direct bilirubin [29 umol/L, range = (0 - 5), BL =normal], normal hemoglobin [135 g/L, range = (130 - 177), BL =low], high lactate dehydrogenase [351 U/L, range = (5 - 250), BL =normal], low protein [57 g/L, range = (60 - 80), BL =normal], and normal urate [357 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 168) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [BILATERAL PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 165) the subject experienced pneumonia [bilateral pneumonia] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 76 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin, and piperacillin/tazobactam.

The subject had the following abnormal laboratory test results at baseline: low glucose [4.3 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 89), the subject had the following on-study laboratory test results with results different than baseline:** low blood urea nitrogen [2.5 mmol/L, range = (2.86 - 8.21), BL =normal], high glucose [8.1 mmol/L, range = (4.6 - 6.4), BL =low], and low sodium [133 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 165) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 54) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 53 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: analgesic or antipyretic agent, atorvastatin, beta blocker, clopidogrel, glycemic control medication, heparin, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [14.56 mg/L, range = (0 - 3)], high urine microscopics [not required, range = NORMAL], high erythrocytes [9-14 /HPF, range = 0-8], high glucose [10.2 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], high occult blood [1+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 54) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 407) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [5.02 mU/L, range = (0.55 - 4.78)], high glucose [7.7 mmol/L, range = (4.1 - 5.9)], high glucose [1+, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high platelets [599 10^9/L, range = (140 - 450)], and high potassium [5.3 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 342), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [negative, range = NEGATIVE, BL =high], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [121 g/L, range = (130 - 175), BL =normal], and low sodium [133 mmol/L, range = (135 - 147), BL =normal].

The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 407) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIO RESPIRATORY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 29) the subject experienced generalised tonic-clonic seizure [generlaize tonic clonic convulsation] (Grade 4) and on PPD (Day 30) the subject experienced cardio-respiratory arrest [cardio respiratory arrest] (Grade 2). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, and clopidogrel.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 30) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): STROKE IN EVOLUTION [STROKE IN PROGRESSION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 15) the subject experienced stroke in evolution [stroke in progression] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the stroke in evolution and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [143 U/L, range = (35 - 104)], and low hemoglobin [107 g/L, range = (116 - 162)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 15) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 554) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [38.21 mg/L, range = (0 - 3)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high erythrocytes [6.1 10^12/L, range = (4.1 - 5.9), BL =normal], high glucose [8.7 mmol/L, range = (4.1 - 5.9), BL =normal], high glucose [1+, range = NEGATIVE, BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 554) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 85) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 84 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [12.5 mg/L, range = (0 - 3)], high alanine aminotransferase [84 U/L, range = (4 - 41)], high aspartate aminotransferase [56 U/L, range = (4 - 37)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatine kinase [208 IU/L, range = (20 - 203)], high glucose [9.9 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [104 g/L, range = (130 - 177)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [303 U/L, range = (5 - 250)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 85) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 311) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [40.25 mg/L, range = (0 - 3)], high alkaline phosphatase [167 U/L, range = (40 - 129)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 187), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and normal urate [393 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 311) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 606) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 266 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, augmentin 500/125mg tds 5 days, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [120 umol/L, range = (62 - 106)], low erythrocytes [3.6 10^12/L, range = (4 - 5.8)], low hemoglobin [122 g/L, range = (130 - 177)], high protein [2+, range = NEGATIVE], and high urate [535 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 340), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [351 U/L, range = (40 - 129), BL =normal], normal blood urea nitrogen [7.85 mmol/L, range = (2.86 - 8.21), BL =high], normal erythrocytes [4.1 10^12/L, range = (4 - 5.8), BL =low], normal hemoglobin [137 g/L, range = (130 - 177), BL =low], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 606) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 550) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 129 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, doxycycline, rochephine, and zinnat.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high creatinine [99 umol/L, range = (44 - 80)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high potassium [5.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [16.76 mg/L, range = (0 - 3), BL =normal], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.4), BL =normal], high leukocytes [13.2 10^9/L, range = (4.1 - 12.3), BL =normal], normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high], and high urate [351 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 550) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 261) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and prasugrel.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [46 U/L, range = (4 - 41)], high creatinine [115 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high glucose [6.1 mmol/L, range = (4.1 - 5.9)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [26 U/L, range = (4 - 41), BL =high], normal creatinine [101 umol/L, range = (62 - 106), BL =high], normal glucose [5.2 mmol/L, range = (4.1 - 5.9), BL =high], and normal leukocytes [0-3 /HPF, range = 0-3, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 261) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 642) the subject experienced death (Grade 4). The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [252 U/L, range = (4 - 41)], high aspartate aminotransferase [251 U/L, range = (4 - 37)], high bilirubin [43 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high calcium [2.6 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55)], high direct bilirubin [15 umol/L, range = (0 - 5)], high glucose [14.9 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [281 U/L, range = (5 - 250)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [21 U/L, range = (4 - 41), BL =high], low alkaline phosphatase [38 U/L, range = (40 - 129), BL =normal], normal aspartate aminotransferase [15 U/L, range = (4 - 37), BL =high], normal bilirubin [15 umol/L, range = (3 - 21), BL =high], normal calcium [2.45 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.45 mmol/L, range = (2.2 - 2.55), BL =high], normal direct bilirubin [5 umol/L, range = (0 - 5), BL =high], normal glucose [5.8 mmol/L, range = (4.6 - 6.4), BL =high], and normal lactate dehydrogenase [167 U/L, range = (5 - 250), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 642) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LARYNGEAL CANCER [LARYNGEAL CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 617) the subject experienced laryngeal cancer (Grade 3) and on PPD (Day 801) the subject died due to laryngeal cancer. The event was considered serious for the following reasons: results in death. The event occurred 57 days after the last dose of any study medication.

Concomitant medications taken at the onset of the laryngeal cancer and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, amoxicillin + clavulanate, analgesic or antipyretic agent, atorvastatin, beta blocker, cefixime, and unknown.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.06 mg/L, range = (0 - 3)], and low glucose [3.9 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 674), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], normal glucose [4.7 mmol/L, range = (4.6 - 6.4), BL =low], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [117 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [266 U/L, range = (5 - 250), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 801) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [ACUTE MASSIVE PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 406) the subject experienced pulmonary embolism [acute massive pulmonary embolism]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 60 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [81 U/L, range = (4 - 41)], high aspartate aminotransferase [39 U/L, range = (4 - 37)], high glucose [8.4 mmol/L, range = (4.1 - 5.9)], high protein [1+, range = NEGATIVE], and high urate [619 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 346), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [29 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [16 U/L, range = (4 - 37), BL =high], high CRP [29.81 mg/L, range = (0 - 3), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 406) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 261) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [9.1 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 261) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 17) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, glycemic control medication, other prescription omega-3 fish oil, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [39 U/L, range = (40 - 129)], high blood urea nitrogen [15.35 mmol/L, range = (2.86 - 8.21)], high creatinine [175 umol/L, range = (62 - 106)], low erythrocytes [3.3 10^12/L, range = (4 - 5.8)], low hematocrit [0.33 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [109 g/L, range = (130 - 177)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [589 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 17) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 212) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 45 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [trace, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [11 U/L, range = (4 - 41), BL = missing], normal alanine aminotransferase [12 U/L, range = (4 - 41), BL = missing], normal albumin [41 g/L, range = (35 - 52), BL = missing], normal albumin [40 g/L, range = (35 - 52), BL = missing], normal alkaline phosphatase [61 U/L, range = (40 - 129), BL = missing], normal alkaline phosphatase [60 U/L, range = (40 - 129), BL = missing], normal aspartate aminotransferase [13 U/L, range = (4 - 37), BL = missing], normal aspartate aminotransferase [14 U/L, range = (4 - 37), BL = missing], normal bilirubin [5 umol/L, range = (3 - 21), BL = missing], normal bilirubin [7 umol/L, range = (3 - 21), BL = missing], high bilirubin [1+, range = NEGATIVE, BL =normal], normal blood urea nitrogen [7.85 mmol/L, range = (2.86 - 8.21), BL = missing], normal blood urea nitrogen [7.14 mmol/L, range = (2.86 - 8.21), BL = missing], normal calcium [2.25 mmol/L, range = (2.2 - 2.55), BL = missing], normal calcium [2.28 mmol/L, range = (2.2 - 2.55), BL = missing], normal calcium corrected [2.25 mmol/L, range = (2.2 - 2.55), BL = missing], normal calcium corrected [2.28 mmol/L, range =

(2.2 - 2.55), BL = missing], normal creatine kinase [90 IU/L, range = (20 - 203), BL = missing], normal creatine kinase [94 IU/L, range = (20 - 203), BL = missing], normal creatinine [90 umol/L, range = (62 - 106), BL = missing], normal creatinine [101 umol/L, range = (62 - 106), BL = missing], normal direct bilirubin [2 umol/L, range = (0 - 5), BL = missing], normal direct bilirubin [2 umol/L, range = (0 - 5), BL = missing], high glucose [12 mmol/L, range = (4.6 - 6.4), BL = missing], high glucose [13.9 mmol/L, range = (4.6 - 6.4), BL = missing], normal glucose [negative, range = NEGATIVE, BL =high], low hemoglobin [124 g/L, range = (130 - 177), BL =normal], normal lactate dehydrogenase [168 U/L, range = (5 - 250), BL = missing], normal lactate dehydrogenase [170 U/L, range = (5 - 250), BL = missing], normal magnesium [0.7 mmol/L, range = (0.65 - 1.05), BL = missing], and.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 212) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 845) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, beta blocker, claritromicina, glycemic control medication, insulin, plurifloxacin, ranolazine, and rivaroxaban.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [14.99 mmol/L, range = (2.86 - 8.21)], high creatinine [173 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [34 mL/min/1.73m2, range = (60 - 9999)], high glucose [10.4 mmol/L, range = (4.6 - 6.4)], high leukocytes [tntc /HPF, range = 0-3], high occult blood [trace, range = NEGATIVE], high potassium [5.8 mmol/L, range = (3.3 - 5.1)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [32 g/L, range = (35

- 52), BL =normal], high bilirubin [24 umol/L, range = (3 - 21), BL =normal], low calcium [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], high direct bilirubin [8 umol/L, range = (0 - 5), BL =normal], normal glucose [5.1 mmol/L, range = (4.6 - 6.4), BL =high], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [110 g/L, range = (130 - 177), BL =normal], normal potassium [4.1 mmol/L, range = (3.3 - 5.1), BL =high], low protein [57 g/L, range = (60 - 80), BL =normal], and normal urate [274 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 845) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 249) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 25 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low platelets [132 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 167), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [tntc /HPF, range = 0-3, BL = missing], high occult blood [trace, range = NEGATIVE, BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 249) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): COLON CANCER [CANCER OF TRANSVERSE COLON]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 291) the subject experienced colon cancer [cancer of transverse colon] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 24 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the colon cancer and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.26 mg/L, range = (0 - 3)], high glucose [9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52), BL =normal], and low hemoglobin [122 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 291) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GASTRIC CANCER [GASTRIC CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 294) the subject experienced gastric cancer (Grade 4) and on PPD (Day 547) the subject died due to gastric cancer (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 14 days after the last dose of any study medication.

Concomitant medications taken at the onset of the gastric cancer and up to 30 days prior to event onset included: levofloxacin tablets [dsep], pitavastatin, and zosyn.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [24 umol/L, range = (3 - 21)], high direct bilirubin [7 umol/L, range = (0 - 5)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [174 U/L, range = (40 - 129), BL =normal], normal bilirubin [10 umol/L, range = (3 - 21), BL =high], normal direct bilirubin [5 umol/L, range = (0 - 5), BL =high], high glucose [6.5 mmol/L, range = (4.6 - 6.4), BL =normal], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [111 g/L, range = (130 - 177), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], and high platelets [526 10^9/L, range = (140 - 450), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 547) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SMALL CELL LUNG CANCER [SMALL CELL LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 267) the subject experienced small cell lung cancer (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 266 days after the last dose of any study medication.

Concomitant medications taken at the onset of the small cell lung cancer and up to 30 days prior to event onset included: pitavastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.85 mg/L, range = (0 - 3)], high erythrocytes [tntc /HPF, range = 0-5], high occult blood [3+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 59), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [115 g/L, range = (130 - 177), BL =normal], low leukocytes [3.7 10^9/L, range = (4.1 - 12.3), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 267) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 220) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline: high bilirubin [26 umol/L, range = (3 - 21), BL =normal], low blood urea nitrogen [2.14 mmol/L, range = (2.86 - 8.21), BL =normal], and high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 220) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 485) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 22 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: pitavastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.9 mmol/L, range = (4.1 - 5.9)], and high glucose [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 485) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE CHRONIC [CHRONIC HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 659) the subject experienced cardiac failure chronic [chronic heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure chronic and up to 30 days prior to event onset included: ceftriaxone sodium hydrate, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.53 mg/L, range = (0 - 3)], low erythrocytes [3.1 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.33 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [106 g/L, range = (130 - 175)], and high potassium [5.3 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [59 U/L, range = (4 - 41), BL =normal], low albumin [33 g/L, range = (35 - 52), BL =normal], high aspartate aminotransferase [57 U/L, range = (4 - 37), BL =normal], high blood urea nitrogen [12.99 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [136 umol/L, range = (62 - 106), BL =normal], normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high], and low sodium [132 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 659) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GASTRIC CANCER [GASTRIC CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 191) the subject experienced gastric cancer (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 101 days after the last dose of any study medication.

Concomitant medications taken at the onset of the gastric cancer and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.37 mg/L, range = (0 - 3)], low erythrocytes [3.4 10^12/L, range = (4 - 5.8)], high glucose [10.3 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.33 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [107 g/L, range = (130 - 177)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 191) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 486) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 51 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline: high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 486) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBELLAR HAEMORRHAGE [HEMORRHAGE CEREBELLAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 956) the subject experienced cerebellar haemorrhage [hemorrhage cerebellar] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebellar haemorrhage and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [12.1 mg/L, range = (0 - 3)], high alanine aminotransferase [54 U/L, range = (4 - 41)], high aspartate aminotransferase [41 U/L, range = (4 - 37)], high bilirubin [1+, range = NEGATIVE], high glucose [7.3 mmol/L, range = (4.1 - 5.9)], and low magnesium [0.6 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 839), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], and normal glucose [6.1 mmol/L, range = (4.6 - 6.4), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 956) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 609) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 20 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: angiotensin receptor blocker, atorvastatin, beta blocker, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.97 mg/L, range = (0 - 3)], and high thyrotropin [5.11 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high erythrocytes [15-30 /HPF, range = 0-5, BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], high occult blood [2+, range = NEGATIVE, BL =normal], and high urate [517 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 609) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 382) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 46 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high creatine kinase [292 IU/L, range = (20 - 203)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], low hemoglobin [123 g/L, range = (130 - 177)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [79 U/L, range = (4 - 41), BL =normal], high alkaline phosphatase [136 U/L, range = (40 - 129), BL =normal], high aspartate aminotransferase [72 U/L, range = (4 - 37), BL =normal], high creatinine [111 umol/L, range = (62 - 106), BL =normal], normal erythrocytes [4.3 10^12/L, range = (4 - 5.8), BL =low], high glucose [7 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [334 U/L, range = (5 - 250), BL =normal], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 382) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 382) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [152 U/L, range = (35 - 104)], and high urate [375 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high creatinine [87 umol/L, range = (44 - 80), BL =normal], high direct bilirubin [9 umol/L, range = (0 - 5), BL =normal], high erythrocytes [9-14 /HPF, range = 0-8, BL =normal], high lactate dehydrogenase [289 U/L, range = (5 - 250), BL =normal], high occult blood [2+, range = NEGATIVE, BL =normal], and high protein [3+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 382) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 126) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.36 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.14 mmol/L, range = (2.86 - 8.21)], high creatinine [170 umol/L, range = (62 - 106)], low erythrocytes [4 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [117 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high potassium [6 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], and high urate [494 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 87), the subject had the following on-study laboratory test results with results different than baseline:** normal urate [268 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 126) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION ACUTE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 30) the subject experienced cardiac failure acute [acute decompensated heart failure] (Grade 4) and acute myocardial infarction [myocardial infarction acute] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.32 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [85 umol/L, range = (44 - 80)], low hemoglobin [107 g/L, range = (110 - 161)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high urate [363 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 30) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ATRIAL FIBRILLATION [PAROXYSMAL ATRIAL FIBRILLATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 353) the subject experienced atrial fibrillation [paroxysmal atrial fibrillation] (Grade 4). The event was considered serious for the following reasons: results in death, and other medically important serious event. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the atrial fibrillation and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, antidepressants, atorvastatin, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.15 mg/L, range = (0 - 3)], high glucose [7.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.5 mmol/L, range = (0.65 - 1.05)], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [2.16 mg/L, range = (0 - 3), BL =high], and normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 353) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION ACUTE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 82) the subject experienced acute myocardial infarction [myocardial infarction acute] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 11 days after the last dose of any study medication.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [19.72 mg/L, range = (0 - 3)], low hematocrit [0.34 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [115 g/L, range = (130 - 175)], high occult blood [1+, range = NEGATIVE], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high protein [1+, range = NEGATIVE], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 4), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 82) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): HEAD INJURY [SEVERE HEAD INJURY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 174) the subject experienced head injury [severe head injury]. The event was considered serious for the following reasons: results in death. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the head injury and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], high leukocytes [13-30 /HPF, range = 0-12, BL =normal], and high occult blood [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 174) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CHEST PAIN [CHEST PAIN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 760) the subject experienced chest pain. The event was considered serious for the following reasons: results in death. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the chest pain and up to 30 days prior to event onset included: atorvastatin, augmentin 1.2g x tds, cefuroxime, ezetimibe, and tazocin.

The subject had the following abnormal laboratory test results at baseline: low glucose [4.2 mmol/L, range = (4.6 - 6.4)], high glucose [1+, range = NEGATIVE], low hemoglobin [128 g/L, range = (130 - 175)], and high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 680), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [30 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [160 U/L, range = (40 - 129), BL =normal], high direct bilirubin [6 umol/L, range = (0 - 5), BL =normal], low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [12.6 mmol/L, range = (4.6 - 6.4), BL =low], normal glucose [negative, range = NEGATIVE, BL =high], low hematocrit [0.33 fraction of 1, range = (0.4 - 0.52), BL =normal], high leukocytes [tntc /HPF, range = 0-3, BL = missing], high occult blood [trace, range = NEGATIVE, BL =normal], and high platelets [499 10^9/L, range = (140 - 450), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 760) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CHRONIC OBSTRUCTIVE PULMONARY DISEASE [COPD EXACERBATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 665) the subject experienced chronic obstructive pulmonary disease [copd exacerbation]. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the chronic obstructive pulmonary disease and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [86 umol/L, range = (44 - 80)], low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], low glucose [4.1 mmol/L, range = (4.6 - 6.4)], and high thyrotropin [6.2 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing], high leukocytes [tntc /HPF, range = 0-12, BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 665) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPTIC SHOCK [SEPTIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 410) the subject experienced cellulitis [cellulitis aggravated] (Grade 4) and on PPD (Day 420) the subject died due to septic shock. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the septic shock and up to 30 days prior to event onset included: amoxicilin/clavulanic acid, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low hematocrit [0.29 fraction of 1, range = (0.33 - 0.46)], high bilirubin [1+, range = NEGATIVE], low calcium [2.15 mmol/L, range = (2.2 - 2.55)], high creatine kinase [185 IU/L, range = (24 - 160)], low erythrocytes [3.7 10^12/L, range = (3.8 - 5.4)], low hemoglobin [105 g/L, range = (110 - 161)], high occult blood [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 343), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [29 g/L, range = (35 - 52), BL =normal], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], high CRP [35.67 mg/L, range = (0 - 3), BL =normal], normal creatine kinase [46 IU/L, range = (24 - 160), BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], and high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 420) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 362) the subject experienced respiratory failure (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 260 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: atorvastatin, and cefalexine.

The subject had the following abnormal laboratory test results at baseline: high CRP [16.64 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], low albumin [31 g/L, range = (35 - 52)], high blood urea nitrogen [12.5 mmol/L, range = (2.14 - 7.14)], high creatinine [118 umol/L, range = (44 - 80)], high erythrocytes [6-8 /HPF, range = 0-8], high glucose [17 mmol/L, range = (4.1 - 5.9)], high glucose [2+, range = NEGATIVE], low hemoglobin [111 g/L, range = (116 - 162)], high HbA1c [0.15 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [253 U/L, range = (5 - 250)], high protein [3+, range = NEGATIVE], low sodium [132 mmol/L, range = (135 - 147)], and high urate [446 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 102), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [126 U/L, range = (35 - 104), BL =normal], normal lactate dehydrogenase [217 U/L, range = (5 - 250), BL =high], low magnesium [0.6 mmol/L, range = (0.65 - 1.05), BL =normal], and normal sodium [135 mmol/L, range = (135 - 147), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 362) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Pulmonary Embolism)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 92) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 77 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [31.01 mg/L, range = (0 - 3)], high thyrotropin [6.4 mU/L, range = (0.55 - 4.78)], low albumin [34 g/L, range = (35 - 52)], high alkaline phosphatase [121 U/L, range = (35 - 104)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], low erythrocytes [3.4 10^12/L, range = (3.8 - 5.4)], high glucose [8.4 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.31 fraction of 1, range = (0.33 - 0.46)], low hemoglobin [99 g/L, range = (110 - 161)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [276 U/L, range = (5 - 250)], and high platelets [502 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 92) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 413) the subject experienced pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 20 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [34.3 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], low albumin [34 g/L, range = (35 - 52)], high creatinine [115 umol/L, range = (62 - 106)], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [1+, range = NEGATIVE], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], normal glucose [6.1 mmol/L, range = (4.6 - 6.4), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], low hemoglobin [117 g/L, range = (130 - 177), BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 413) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SOFT TISSUE INFECTION [SOFT TISSUE INFECTION NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 78) the subject experienced soft tissue infection [soft tissue infection nos] (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 5 days after the last dose of any study medication.

Concomitant medications taken at the onset of the soft tissue infection and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high creatinine [124 umol/L, range = (62 - 106)], high glucose [10.6 mmol/L, range = (4.6 - 6.4)], low hemoglobin [124 g/L, range = (130 - 177)], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 78) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 147) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 64 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.56 mg/L, range = (0 - 3)], high alkaline phosphatase [107 U/L, range = (35 - 104)], high glucose [13.7 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], and high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 83), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.14 - 7.14), BL =normal], and high creatinine [83 umol/L, range = (44 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 147) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE KIDNEY INJURY [ACUTE ON CHRONIC RENAL FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Renal)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 119) the subject experienced acute kidney injury [acute on chronic renal failure] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and requires or prolongs hospitalization. The event occurred 34 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute kidney injury and up to 30 days prior to event onset included: ampula amikacin 500 mg every 24 hours for 5 days, atorvastatin, and lincomycin ampula 600mg every 24 hours for 3 days.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.41 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [24 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [6.12 mU/L, range = (0.55 - 4.78)], low albumin [32 g/L, range = (35 - 52)], high blood urea nitrogen [18.21 mmol/L, range = (2.86 - 8.21)], high creatinine [166 umol/L, range = (44 - 80)], high glucose [trace, range = NEGATIVE], low hematocrit [0.34 fraction of 1, range = (0.35 - 0.47)], low hemoglobin [111 g/L, range = (116 - 162)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [3+, range = NEGATIVE], and high urate [422 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.3 10^12/L, range = (3.8 - 5.5), BL =normal], low glucose [<2.2 mmol/L, BL =normal], high leukocytes [15.9 10^9/L, range = (4.1 - 12.3), BL =normal], and high magnesium [1.2 mmol/L, range = (0.65 - 1.05), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 119) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): HODGKIN'S DISEASE [LYMPHOMA HODGKIN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 484) the subject experienced hodgkin's disease [lymphoma hodgkin] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the hodgkin's disease and up to 30 days prior to event onset included: acrodantina, atorvastatin, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [229 IU/L, range = (20 - 203)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 338), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [121 IU/L, range = (20 - 203), BL =high], high glucose [6.4 mmol/L, range = (4.6 - 6.4), BL =normal], and low hemoglobin [129 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 484) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [RESPIRATION FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 550) the subject experienced respiratory failure [respiration failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 133 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal urate [375 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 550) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFRACTION (DEATH)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 268) the subject experienced acute myocardial infarction [acute myocardial infraction (death)] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 229 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.69 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 268) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BACTERIAL INFECTION [INFECTION BACTERIAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 33) the subject experienced pneumonia aspiration [aspiration pneumonia] (Grade 4) and on PPD (Day 57) the subject died due to the event. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the bacterial infection and up to 30 days prior to event onset included: cefuroxim, and gentamycine.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.52 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high glucose [9.8 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 57) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 775) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 32 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: ACE inhibitor, acenocoumerol, atorvastatin, ceftazidim, flucloxacillin, and flucloxacilline.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.72 mg/L, range = (0 - 3)], high glucose [7.3 mmol/L, range = (4.6 - 6.4)], low hemoglobin [128 g/L, range = (130 - 175)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [309 U/L, range = (5 - 250)], low magnesium [0.55 mmol/L, range = (0.65 - 1.05)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high blood urea nitrogen [9.1 mmol/L, range = (2.86 - 8.21), BL =normal], low calcium [2.02 mmol/L, range = (2.1 - 2.58), BL =normal], low calcium corrected [2.03 mmol/L, range = (2.1 - 2.58), BL =normal], low erythrocytes [3.3 10^12/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.32 fraction of 1, range = (0.4 - 0.52), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], high leukocytes [13-30 /HPF, range = 0-3, BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 775) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 233) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 6 days after the last dose of any study medication.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.43 mg/L, range = (0 - 3)], high alanine aminotransferase [43 U/L, range = (4 - 41)], and high creatinine [110 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [33 U/L, range = (4 - 41), BL =high], and normal creatinine [99 umol/L, range = (62 - 106), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 233) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): FOETAL DEATH [DEATH FETAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1033) the subject experienced foetal death [death fetal] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 24 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the foetal death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.21 mg/L, range = (0 - 3)], low blood urea nitrogen [2.14 mmol/L, range = (2.86 - 8.21)], and low glucose [4.1 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [4.28 mmol/L, range = (2.86 - 8.21), BL =low], normal glucose [5.1 mmol/L, range = (4.6 - 6.4), BL =low], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1033) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 612) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 503 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [11.3 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 81), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [290 IU/L, range = (24 - 250), BL =normal], low creatinine [61 umol/L, range = (62 - 106), BL =normal], and high lactate dehydrogenase [254 U/L, range = (5 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 612) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): EMBOLIC PNEUMONIA [EMBOLIC PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Non-Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 746) the subject experienced shock haemorrhagic [haemorargisch shock due to abdominal bleeding in liver en lungs] (Grade 4) and on PPD (Day 748) the subject died due to embolic pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 21 days after the last dose of any study medication.

Concomitant medications taken at the onset of the embolic pneumonia and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [108 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 671), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], low hemoglobin [127 g/L, range = (130 - 177), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal urate [404 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 748) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 751) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 188 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [58.89 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [24 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [191 umol/L, range = (62 - 106)], high glucose [9.7 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], low platelets [130 10^9/L, range = (140 - 450)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 684), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.9 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [120 g/L, range = (130 - 177), BL =normal], high leukocytes [13.4 10^9/L, range = (4.1 - 12.3), BL =normal], normal magnesium [0.75 mmol/L, range = (0.65 - 1.05), BL =low], normal platelets [203 10^9/L, range = (140 - 450), BL =low], and high urate [601 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 751) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION ACUTE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 99) the subject experienced acute myocardial infarction [myocardial infarction acute] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 1 days after the last dose of any study medication.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, beta blocker, glycemic control medication, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.1 mmol/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 99) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Hepatobiliary)

Subject PPD was a P_-year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 934) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 793 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: benzylpenicillin, ceftriaxon, chlooramfenicol creme, ezetimibe, norfloxacine, simvastatin, trafoxal eyedrops, valaciclovir, and zovirax creme.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.49 mU/L, range = (0.55 - 4.78)], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low leukocytes [4 10^9/L, range = (4.1 - 12.3)], high occult blood [trace, range = NEGATIVE], low platelets [95 10^9/L, range = (140 - 450)], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 934) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 439) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 438 days after the first dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acenocoumerol, augmentin, beta blocker, ezetimibe, floxapen, glycemic control medication, insulin, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [14.52 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [36 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [14.99 mmol/L, range = (2.86 - 8.21)], high creatinine [155 umol/L, range = (62 - 106)], high glucose [11.4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], and high urate [559 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 341), the subject had the following on-study laboratory test results with results different than baseline:** high potassium [5.5 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 439) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P[redacted]-year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 669) the subject experienced death. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 93 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amoxiciline/clavulaanacid, atorvastatin, benzylpenicilline 6dd 1me, clarithromycin, and nitrofurantoïne.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [7.66 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL = missing], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], normal glucose [negative, range = NEGATIVE, BL = missing], high leukocytes [13-30 /HPF, range = 0-12, BL = missing], normal occult blood [negative, range = NEGATIVE, BL = missing], normal protein [negative, range = NEGATIVE, BL = missing], normal specific gravity [1.02, range = (1 - 1.04), BL = missing], and normal ph [6.5, range = (5 - 8), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 669) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [PULMONARY MALIGNANCY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 928) the subject experienced lung neoplasm malignant [pulmonary malignancy]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 73 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: amoxicilline 500mg, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.18 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high protein [2+, range = NEGATIVE], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [111 umol/L, range = (62 - 106)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], low platelets [126 10^9/L, range = (140 - 450)], and high urate [482 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [172 U/L, range = (40 - 129), BL =normal], normal blood urea nitrogen [7.03 mmol/L, range = (2.86 - 8.21), BL =high], normal creatinine [105 umol/L, range = (62 - 106), BL =high], high glucose [7.4 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [295 U/L, range = (5 - 250), BL =normal], and normal platelets [157 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 928) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): APNOEA [APNEA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 667) the subject experienced apnoea [apnea] (Grade 4) and on PPD (Day 670) the subject died due to the event. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 39 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the apnoea and up to 30 days prior to event onset included: atorvastatin, and nitrofurantoine.

The subject had the following abnormal laboratory test results at baseline: low platelets [133 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and normal platelets [160 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 670) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION ACUTE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P-year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 219) the subject experienced acute myocardial infarction [myocardial infarction acute] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [6-8 /HPF, range = 0-8], and low glucose [4.5 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [4.8 mmol/L, range = (4.6 - 6.4), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 219) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): NECROTISING FASCIITIS [NECROTISING FASCIITIS SCROTUM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 470) the subject experienced necrotising fasciitis [necrotising fasciitis scrotum] (Grade 3) and PPD (Day 474) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 53 days after the last dose of any study medication.

Concomitant medications taken at the onset of the necrotising fasciitis and up to 30 days prior to event onset included: amoxicilline, atorvastatin, ciprofloxacine, ezetimibe, flucloxacilline, gentamicine, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], low calcium [2.08 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2.08 mmol/L, range = (2.2 - 2.55)], high creatine kinase [276 IU/L, range = (20 - 203)], high glucose [9.4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], and low magnesium [0.35 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [14.99 mmol/L, range = (2.86 - 8.21), BL =normal], normal calcium [2.23 mmol/L, range = (2.2 - 2.55), BL =low], normal calcium corrected [2.23 mmol/L, range = (2.2 - 2.55), BL =low], normal creatine kinase [89 IU/L, range = (20 - 203), BL =high], high creatinine [159 umol/L, range = (62 - 106), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], normal magnesium [0.75 mmol/L, range =

(0.65 - 1.05), BL =low], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and high urate [565 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 474) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 135) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 49 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [83 U/L, range = (4 - 41)], high aspartate aminotransferase [60 U/L, range = (4 - 37)], high leukocytes [4-12 /HPF, range = 0-3], low platelets [133 10^9/L, range = (140 - 450)], and high urate [506 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [31 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [26 U/L, range = (4 - 37), BL =high], and normal platelets [145 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 135) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 940) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, amoxicilline, analgesic or antipyretic agent, atorvastatin, beta blocker, doxicycline, doxycicline, flucloxacilline, fraxiparin, hormone replacement therapy, oral corticosteroids, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [5.56 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 839), the subject had the following on-study laboratory test results with results different than baseline:** low glucose [4.5 mmol/L, range = (4.6 - 6.4), BL =normal], high leukocytes [tntc /HPF, range = 0-3, BL =normal], and high occult blood [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 940) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 545) the subject experienced glioblastoma multiforme [glioblastoma multiforme grade 4] (Grade 4) and on PPD (Day 843) the subject died. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 294 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amoxicilline, atorvastatin, augmentin, ciproxin, cotrimoxazol, and gentamycine.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.41 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 843) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [SUDDEN CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 672) the subject experienced cardiac arrest [sudden cardiac arrest] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 15 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.55 mg/L, range = (0 - 3)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 657), the subject had the following on-study laboratory test results with results different than baseline:** high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal potassium [4.5 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 672) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 42) the subject experienced metastatic bronchial carcinoma [bronchus carcinoma with metastasis] (Grade 3) and on PPD (Day 430) the subject died due to the event. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 190 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, analgesic or antipyretic agent, augmentin, ciprofloxacine, oral corticosteroids, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.06 mg/L, range = (0 - 3)], low creatinine [61 umol/L, range = (62 - 106)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], low hemoglobin [126 g/L, range = (130 - 177)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [75 umol/L, range = (62 - 106), BL =low], normal glucose [6 mmol/L, range = (4.6 - 6.4), BL =high], normal hemoglobin [144 g/L, range = (130 - 177), BL =low], normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 430) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 300) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [122 U/L, range = (35 - 104)], high calcium [2.63 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58)], high creatinine [81 umol/L, range = (44 - 80)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], and high urate [363 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [79 umol/L, range = (44 - 80), BL =high], high hematocrit [0.49 fraction of 1, range = (0.35 - 0.47), BL =normal], high leukocytes [14 10^9/L, range = (4.1 - 12.3), BL =normal], normal potassium [4.8 mmol/L, range = (3.3 - 5.1), BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 300) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): COMPLETED SUICIDE [PPD]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Suicide)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 188) the subject experienced completed suicide [PPD] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the completed suicide and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, and ticagrelor.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [55 U/L, range = (4 - 41)], high aspartate aminotransferase [43 U/L, range = (4 - 37)], and low erythrocytes [4 10^12/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 173), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [32 U/L, range = (4 - 41), BL =high], high bilirubin [1+, range = NEGATIVE, BL =normal], high creatine kinase [325 IU/L, range = (24 - 250), BL =normal], normal erythrocytes [4.5 10^12/L, range = (4.1 - 5.9), BL =low], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [6.5 mmol/L, range = (4.1 - 5.9), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 188) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [ASYSTOLE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 525) the subject experienced cardiac arrest [asystole] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: ACE inhibitor, beta blocker, phenprocoumon, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high potassium [5.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high occult blood [trace, range = NEGATIVE, BL =normal], normal potassium [4.3 mmol/L, range = (3.3 - 5.1), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 525) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 691) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 77 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and doxycyclin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 503), the subject had the following on-study laboratory test results with results different than baseline: high lactate dehydrogenase [254 U/L, range = (5 - 250), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and low urate [161 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 691) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 503) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high creatinine [135 umol/L, range = (62 - 106)], high erythrocytes [6-8 /HPF, range = 0-5], and high glucose [8.2 mmol/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.6 mmol/L, range = (2.14 - 7.14), BL =normal], normal creatinine [88 umol/L, range = (62 - 106), BL =high], normal glucose [5.4 mmol/L, range = (4.1 - 5.9), BL =high], and normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 503) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 338) the subject experienced cardiac failure [heart failure] (Grade 4) and died. The event was considered serious for the following reasons: results in death. The event occurred 78 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [160 U/L, range = (35 - 104)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.5 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 338) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 462) the subject experienced small cell lung cancer metastatic [progression of metastatic small cell lung cancer] (Grade 3) and on PPD (Day 485) the subject died. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 231 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amoxicillin + clavulanic, amoxicillin trihydrate, analgesic or antipyretic agent, atorvastatin, augmentin, azithromycin, and iv amoxicillin + clavulanic.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [140 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], and high urate [708 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [129 g/L, range = (130 - 177), BL =normal], and normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 485) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA ASPIRATION [ASPIRATION PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1148) the subject experienced pneumonia aspiration [aspiration pneumonia] (Grade 4). The event was considered serious for the following reasons: results in death, and other medically important serious event. The event occurred 109 days after the last dose of any study medication.

Concomitant medications taken at the onset of the pneumonia aspiration and up to 30 days prior to event onset included: amoxicillin, atorvastatin, augmentin, and co-trimoxazole.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [302 IU/L, range = (24 - 250)], high protein [trace, range = NEGATIVE], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [120 IU/L, range = (24 - 250), BL =high], and normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1148) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIOPULMONARY ARREST SECONDARY TO CARDIAC ARREST DISEASE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 741) the subject experienced cardio-respiratory arrest [cardiopulmonary arrest secondary to cardiac arrest disease] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [85 umol/L, range = (44 - 80)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high sodium [148 mmol/L, range = (135 - 147)], high urate [434 umol/L, range = (143 - 339)], and low erythrocytes [3.7 10^12/L, range = (3.8 - 5.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 674), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [78 umol/L, range = (44 - 80), BL =high], normal erythrocytes [3.8 10^12/L, range = (3.8 - 5.4), BL =low], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], normal leukocytes [0-3 /HPF, range = 0-12, BL = missing], high protein [1+, range = NEGATIVE, BL =normal], and normal sodium [146 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 741) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEAD ON ARRIVAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 47) the subject experienced death [dead on arrival] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 46 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [16.42 mmol/L, range = (2.14 - 7.14)], high creatinine [182 umol/L, range = (62 - 106)], high glucose [8.9 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high urate [517 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 47) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 438) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, angiotensin receptor blocker, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [21 mL/min/1.73m2, range = (60 - 9999)], low albumin [33 g/L, range = (35 - 52)], high blood urea nitrogen [16.07 mmol/L, range = (2.86 - 8.21)], high creatinine [213 umol/L, range = (44 - 80)], high glucose [trace, range = NEGATIVE], low hematocrit [0.32 fraction of 1, range = (0.35 - 0.47)], low hemoglobin [107 g/L, range = (116 - 162)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high occult blood [1+, range = NEGATIVE], high potassium [6 mmol/L, range = (3.3 - 5.1)], high protein [3+, range = NEGATIVE], and high urate [630 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [186 U/L, range = (35 - 104), BL =normal], high creatine kinase [249 IU/L, range = (24 - 170), BL =normal], low erythrocytes [3.3 10^12/L, range = (3.8 - 5.5), BL =normal], low glucose [3.9 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [287 U/L, range = (5 - 250), BL =normal], normal potassium [4.5 mmol/L, range = (3.3 - 5.1), BL =high], and low protein [58 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 438) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE CORONARY SYNDROME [ACUTE CORONARY SYNDROME]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 408) the subject experienced acute coronary syndrome (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 407 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute coronary syndrome and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.98 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high creatinine [177 umol/L, range = (62 - 106)], high protein [1+, range = NEGATIVE], high protein [81 g/L, range = (60 - 80)], and high urate [571 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [10.35 mmol/L, range = (2.14 - 7.14), BL =normal], normal CRP [0.98 mg/L, range = (0 - 3), BL =high], normal protein [negative, range = NEGATIVE, BL =high], normal protein [76 g/L, range = (60 - 80), BL =high], and high sodium [148 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 408) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPTIC SHOCK [SEPTIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 89) the subject experienced septic shock (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the septic shock and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.09 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [36 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [183 U/L, range = (35 - 104)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatinine [140 umol/L, range = (44 - 80)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], and high urate [571 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 89) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 754) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [27.05 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.07 mmol/L, range = (2.86 - 8.21)], high creatinine [145 umol/L, range = (62 - 106)], low erythrocytes [3.5 10^12/L, range = (4 - 5.8)], low hematocrit [0.33 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [106 g/L, range = (130 - 177)], high leukocytes [15.6 10^9/L, range = (4.1 - 12.3)], high potassium [5.7 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], and high urate [636 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [15 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [159 U/L, range = (40 - 129), BL =normal], low calcium [1.94 mmol/L, range = (2.2 - 2.55), BL =normal], high erythrocytes [9-14 /HPF, range = 0-5, BL = missing], high glucose [2+, range = NEGATIVE, BL =normal], normal leukocytes [11.1 10^9/L, range = (4.1 - 12.3), BL =high], high occult blood [3+, range = NEGATIVE, BL =normal], normal potassium [4.7 mmol/L, range = (3.3 - 5.1), BL =high], normal protein [4+, range = NEGATIVE, BL =high], low protein [51 g/L, range = (60 - 80), BL =normal], and low sodium [129 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 754) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 48) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [35 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [57 U/L, range = (4 - 41)], high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], high creatinine [170 umol/L, range = (62 - 106)], high glucose [12.4 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high leukocytes [12.4 10^9/L, range = (4.1 - 12.3)], high protein [1+, range = NEGATIVE], and high protein [87 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 48) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history include PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 486) the subject experienced death [death nos] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and azithromycin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.67 mg/L, range = (0 - 3)], high creatinine [107 umol/L, range = (62 - 106)], high glucose [6 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [613 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 339), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [1.82 mg/L, range = (0 - 3), BL =high], normal creatinine [106 umol/L, range = (62 - 106), BL =high], normal glucose [4.8 mmol/L, range = (4.1 - 5.9), BL =high], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], and high sodium [148 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 486) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPTIC SHOCK [SEPTIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 390) the subject experienced septic shock (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the septic shock and up to 30 days prior to event onset included: atorvastatin, cefuroxime, ciprofloxacin, clindamycin, and cotrimoxazole.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.55 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [112 U/L, range = (35 - 104)], high glucose [14.3 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.14 fraction of 1, range = (0.04 - 0.06)], high leukocytes [13-30 /HPF, range = 0-12], high occult blood [1+, range = NEGATIVE], high protein [trace, range = NEGATIVE], high protein [85 g/L, range = (60 - 80)], and low sodium [134 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 349), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 390) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BRAIN HERNIATION [BRAIN HERNIATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 264) the subject experienced brain herniation (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the brain herniation and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.08 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14)], high creatine kinase [255 IU/L, range = (24 - 250)], high creatinine [146 umol/L, range = (62 - 106)], high glucose [6.1 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], high occult blood [1+, range = NEGATIVE], high protein [3+, range = NEGATIVE], and high urate [547 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 88), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [238 IU/L, range = (24 - 250), BL =high], and normal glucose [5.4 mmol/L, range = (4.1 - 5.9), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 264) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [SUDDEN CARDIAC DEATH PROBABLY SECONDARY TO MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 432) the subject experienced myocardial infarction [sudden cardiac death probably secondary to myocardial infarction] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high albumin [53 g/L, range = (35 - 52)], high calcium [2.7 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.7 mmol/L, range = (2.1 - 2.58)], and high protein [87 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 342), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [45 U/L, range = (4 - 41), BL =normal], normal albumin [47 g/L, range = (35 - 52), BL =high], high CRP [4.33 mg/L, range = (0 - 3), BL =normal], normal calcium [2.51 mmol/L, range = (2.1 - 2.58), BL =high], normal calcium corrected [2.5 mmol/L, range = (2.1 - 2.58), BL =high], high leukocytes [4-12 /HPF, range = 0-3, BL = missing], normal protein [78 g/L, range = (60 - 80), BL =high], and high urate [428 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 432) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 466) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 38 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: amikacin, atorvastatin, azythromycin 500 mg 1 tab od, cefipime, cefixime 400 mg od, and sulbactam-ampicillin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [107 umol/L, range = (62 - 106)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 343), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [4.11 mg/L, range = (0 - 3), BL =normal], normal creatinine [101 umol/L, range = (62 - 106), BL =high], high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [272 U/L, range = (5 - 250), BL =normal], and high urate [452 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 466) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEAD ON ARRIVAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 432) the subject experienced death [dead on arrival] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: angiotensin receptor blocker, atorvastatin, and cilostazol.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [21 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.07 mmol/L, range = (2.86 - 8.21)], high creatinine [260 umol/L, range = (62 - 106)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], low glucose [4.5 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [111 g/L, range = (130 - 177)], high protein [3+, range = NEGATIVE], and high urate [553 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [16.67 mg/L, range = (0 - 3), BL =normal], normal glucose [5.5 mmol/L, range = (4.6 - 6.4), BL =low], and normal urate [369 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 432) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 260) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [44 U/L, range = (4 - 31)], high calcium [2.65 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55)], high creatinine [127 umol/L, range = (44 - 80)], low glomerular filtration rate, estimated [36 mL/min/1.73m2, range = (60 - 9999)], high glucose [8.9 mmol/L, range = (4.6 - 6.4)], high occult blood [trace, range = NEGATIVE], high protein [trace, range = NEGATIVE], and high urate [357 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [113 U/L, range = (35 - 104), BL =normal], normal aspartate aminotransferase [30 U/L, range = (4 - 31), BL =high], high erythrocytes [6-8 /HPF, range = 0-8, BL =normal], normal glucose [5.3 mmol/L, range = (4.6 - 6.4), BL =high], and high lactate dehydrogenase [280 U/L, range = (5 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 260) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE RESPIRATORY FAILURE [ACUTE RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 18) the subject experienced mass [oropharyngeal mass] (Grade 4) and on PPD (Day 24) the subject experienced acute respiratory failure (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute respiratory failure and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, glycemic control medication, and over the counter omega-3 fish oil.

The subject had the following abnormal laboratory test results at baseline: high CRP [33.53 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [35 mL/min/1.73m2, range = (60 - 9999)], high aspartate aminotransferase [36 U/L, range = (4 - 31)], high calcium [2.73 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.73 mmol/L, range = (2.2 - 2.55)], high creatinine [154 umol/L, range = (44 - 80)], high glucose [12.5 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [407 U/L, range = (5 - 250)], high leukocytes [31-50 /HPF, range = 0-12], high occult blood [trace, range = NEGATIVE], high protein [82 g/L, range = (60 - 80)], and high urate [732 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 24) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 471) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high creatinine [95 umol/L, range = (44 - 80)], high protein [trace, range = NEGATIVE], and high urate [399 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 332), the subject had the following on-study laboratory test results with results different than baseline:** normal urate [333 umol/L, range = (143 - 339), BL=high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 471) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 597) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 596 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [42.97 mg/L, range = (0 - 3)], high alanine aminotransferase [44 U/L, range = (4 - 41)], high alkaline phosphatase [274 U/L, range = (40 - 129)], high bilirubin [1+, range = NEGATIVE], high platelets [580 10^9/L, range = (140 - 450)], high protein [1+, range = NEGATIVE], and high protein [93 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 499), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [13 U/L, range = (4 - 41), BL =high], normal alkaline phosphatase [74 U/L, range = (40 - 129), BL =high], normal bilirubin [negative, range = NEGATIVE, BL =high], low blood urea nitrogen [2.53 mmol/L, range = (2.86 - 8.21), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], normal platelets [317 10^9/L, range = (140 - 450), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and high urate [630 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 597) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CELLULITIS [CELLULITIS AGGRAVATED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 181) the subject experienced cellulitis [cellulitis aggravated] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cellulitis and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [64 U/L, range = (4 - 41)], high aspartate aminotransferase [58 U/L, range = (4 - 37)], high creatine kinase [253 IU/L, range = (20 - 203)], high glucose [trace, range = NEGATIVE], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [305 U/L, range = (5 - 250)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [26 U/L, range = (4 - 41), BL =high], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [111 umol/L, range = (62 - 106), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], normal glucose [negative, range = NEGATIVE, BL =high], high leukocytes [17.7 10^9/L, range = (4.1 - 12.3), BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 181) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBRAL HAEMORRHAGE [CEREBRAL HAEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 402) the subject experienced cerebral haemorrhage (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebral haemorrhage and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.7 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [3.31 mg/L, range = (0 - 3), BL =normal], high glucose [3+, range = NEGATIVE, BL =normal], and normal hematocrit [0.46 fraction of 1, range = (0.4 - 0.52), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 402) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 503) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, clopidogrel, and levofloxacin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [53 U/L, range = (4 - 41)], and high aspartate aminotransferase [46 U/L, range = (4 - 37)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 499), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [15 U/L, range = (4 - 41), BL =high], low albumin [25 g/L, range = (35 - 52), BL =normal], normal aspartate aminotransferase [21 U/L, range = (4 - 37), BL =high], high blood urea nitrogen [10.5 mmol/L, range = (2.86 - 8.21), BL =normal], low calcium [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], low erythrocytes [3.2 10^12/L, range = (4 - 5.8), BL =normal], high glucose [6.9 mmol/L, range = (4.6 - 6.4), BL =normal], low hematocrit [0.31 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [99 g/L, range = (130 - 177), BL =normal], high leukocytes [20.8 10^9/L, range = (4.1 - 12.3), BL =normal], low protein [50 g/L, range = (60 - 80), BL =normal], and low urate [184 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 503) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SEPTIC SHOCK [SEPTIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 245) the subject experienced septic shock (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the septic shock and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], and high creatinine [110 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [13-30 /HPF, range = 0-3, BL = missing], high occult blood [trace, range = NEGATIVE, BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and high protein [82 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 245) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 287) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.41 mg/L, range = (0 - 3)], high erythrocytes [31-50 /HPF, range = 0-8], low glomerular filtration rate, estimated [34 mL/min/1.73m2, range = (60 - 9999)], high occult blood [3+, range = NEGATIVE], high protein [1+, range = NEGATIVE], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [143 umol/L, range = (44 - 80)], high glucose [10.4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high leukocytes [12.7 10^9/L, range = (4.1 - 12.3)], high protein [81 g/L, range = (60 - 80)], and high urate [440 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 176), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [1+, range = NEGATIVE, BL =normal], and high leukocytes [13-30 /HPF, range = 0-12, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 287) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 597) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, azithromycin 500 mg, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [14.33 mg/L, range = (0 - 3)], and high creatine kinase [209 IU/L, range = (24 - 170)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 502), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [157 IU/L, range = (24 - 160), BL =high], and high leukocytes [13-30 /HPF, range = 0-12, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 597) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [CARDIOVASCULAR DEATH - POST SURGICAL CORONARY REVASCULARISATION (OPCAB)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Procedures)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 554) the subject experienced cardiac failure [heart failure] (Grade 4) and myocardial infarction (Grade 4). On PPD (Day 554) the subject experienced cardiovascular disorder [cardiovascular death - post surgical coronary revascularisation (opcab)] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 5 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: amoksiklav, amoxicilin, atorvastatin, ciphin, and nolicin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.22 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high creatinine [108 umol/L, range = (62 - 106)], high glucose [7.9 mmol/L, range = (4.6 - 6.4)], and high urate [595 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [102 umol/L, range = (62 - 106), BL =high], and low hemoglobin [125 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 554) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 490) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 489 days after the first dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [163 U/L, range = (40 - 129)], high glucose [8.9 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 333), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [6.2 mmol/L, range = (4.6 - 6.4), BL =high], and high sodium [150 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 490) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): POST PROCEDURAL COMPLICATION [THYREIDECTOMIA-COMPLICATION AFTER OPERATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Non-Cardiovascular Procedure Or Surgery)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 199) the subject experienced cardiac failure [heart failure, unspecified] (Grade 4) and on PPD (Day 223) the subject experienced post procedural complication [thyreidectomia-complication after operation] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 53 days after the last dose of any study medication.

Concomitant medications taken at the onset of the post procedural complication and up to 30 days prior to event onset included: atorvastatin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [24 umol/L, range = (3 - 21)], high glucose [7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 223) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GASTROINTESTINAL NECROSIS [SMALL INTESTINAL NECROSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Intestinal Ischemia)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 102) the subject experienced thrombosis mesenteric vessel [thrombus of mesentery] (Grade 4) and on PPD (Day 106) the subject experienced gastrointestinal necrosis [small intestinal necrosis] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastrointestinal necrosis and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.44 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high erythrocytes [6-8 /HPF, range = 0-5], high occult blood [2+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 89), the subject had the following on-study laboratory test results with results different than baseline:** high protein [82 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 106) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 505) the subject experienced lung neoplasm malignant [disseminated lung cancer] (Grade 4) and on PPD (Day 561) the subject died due to the event. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 70 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.34 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 523), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [16.5 10^9/L, range = (4.1 - 12.3), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 561) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 658) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 76 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high albumin [53 g/L, range = (35 - 52)], high bilirubin [1+, range = NEGATIVE], and high protein [82 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 507), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [45 U/L, range = (4 - 41), BL =normal], normal albumin [46 g/L, range = (35 - 52), BL =high], low creatinine [57 umol/L, range = (62 - 106), BL =normal], high hematocrit [0.53 fraction of 1, range = (0.4 - 0.52), BL =normal], high protein [1+, range = NEGATIVE, BL =normal], and normal protein [74 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 658) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 335) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline:** normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 335) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 829) the subject experienced sudden cardiac death. The event was considered serious for the following reasons: results in death. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high calcium [2.63 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55)], and high glucose [6.8 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [43 U/L, range = (4 - 41), BL =normal], normal calcium [2.5 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.5 mmol/L, range = (2.2 - 2.55), BL =high], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [476 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 829) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 627) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 122 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [5.05 mU/L, range = (0.55 - 4.78)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 627) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 215) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [52 U/L, range = (4 - 41)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** normal urate [333 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 215) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): UPPER GASTROINTESTINAL HAEMORRHAGE [UPPER GASTROINTESTINAL BLEEDING]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 130) the subject experienced upper gastrointestinal haemorrhage [upper gastrointestinal bleeding] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 46 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the upper gastrointestinal haemorrhage and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low bilirubin [2 umol/L, range = (3 - 21)], low erythrocytes [3.7 10^12/L, range = (3.8 - 5.5)], low hematocrit [0.33 fraction of 1, range = (0.35 - 0.47)], low hemoglobin [109 g/L, range = (116 - 162)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and low urate [59 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 84), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [217 IU/L, range = (24 - 170), BL =normal], and normal erythrocytes [3.9 10^12/L, range = (3.8 - 5.5), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 130) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 301) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 300 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.81 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high creatinine [126 umol/L, range = (44 - 80)], high glucose [7.3 mmol/L, range = (4.6 - 6.4)], and high urate [583 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high occult blood [trace, range = NEGATIVE, BL =normal], and normal urate [280 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be related to IP and related to statin. The event ended on PPD (Day 301) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 760) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 255 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amoxiccilinum with accidum clavulanicum, atorvastatin, ceftriaxone, ciprofloxacin, clindamycin, and metronidazole.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.91 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [32 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.5 mmol/L, range = (2.86 - 8.21)], high creatinine [163 umol/L, range = (62 - 106)], low erythrocytes [3.4 10^12/L, range = (4 - 5.8)], low hematocrit [0.32 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [108 g/L, range = (130 - 177)], high magnesium [1.1 mmol/L, range = (0.65 - 1.05)], high potassium [6 mmol/L, range = (3.3 - 5.1)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal magnesium [0.95 mmol/L, range = (0.65 - 1.05), BL =high], and normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 760) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 588) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 196 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amotaks, augmentin, biseptol, cefazolin, ciprinol, ciprofloxacin, cipronex, klabion, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high erythrocytes [tntc /HPF, range = 0-5], low hemoglobin [124 g/L, range = (130 - 177)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high leukocytes [18.8 10^9/L, range = (4.1 - 12.3)], high occult blood [3+, range = NEGATIVE], high protein [2+, range = NEGATIVE], low protein [57 g/L, range = (60 - 80)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 525), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [13.39 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [118 umol/L, range = (62 - 106), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], and high leukocytes [31-50 /HPF, range = 0-3, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 588) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 563) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 127 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: dalacin, octenisept, and simvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline: high CRP [7.8 mg/L, range = (0 - 3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 563) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ABDOMINAL NEOPLASM [ABDOMINAL TUMOR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 767) the subject experienced abdominal neoplasm [abdominal tumor] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 24 days after the last dose of any study medication.

Concomitant medications taken at the onset of the abdominal neoplasm and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [114 g/L, range = (130 - 175), BL =normal], high lactate dehydrogenase [304 U/L, range = (5 - 250), BL =normal], and normal leukocytes [0-3 /HPF, range = 0-3, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 767) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): EXTRADURAL HAEMATOMA [EPIDURAL HEMATOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 644) the subject experienced extradural haematoma [epidural hematoma] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 27 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the extradural haematoma and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [73 U/L, range = (4 - 41)], high aspartate aminotransferase [105 U/L, range = (4 - 37)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [251 U/L, range = (5 - 250)], high protein [1+, range = NEGATIVE], and high urate [529 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 500), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [23 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [36 U/L, range = (4 - 37), BL =high], high bilirubin [2+, range = NEGATIVE, BL =normal], high calcium [2.63 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55), BL =normal], high creatinine [116 umol/L, range = (62 - 106), BL =normal], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], normal glucose [5.2 mmol/L, range = (4.6 - 6.4), BL =high], normal lactate dehydrogenase [185 U/L, range = (5 - 250), BL =high], and high leukocytes [13-30 /HPF, range = 0-3, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 644) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 799) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: klarytromycyna, simvastatin, and tobradex.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], high creatinine [111 umol/L, range = (62 - 106)], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 502), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.78 mmol/L, range = (2.86 - 8.21), BL =high], normal creatinine [106 umol/L, range = (62 - 106), BL =high], normal glucose [6.3 mmol/L, range = (4.6 - 6.4), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 799) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 568) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 56 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [42 U/L, range = (4 - 41)], high aspartate aminotransferase [40 U/L, range = (4 - 37)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high creatine kinase [300 IU/L, range = (24 - 250)], and high urate [607 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 512), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [31 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [30 U/L, range = (4 - 37), BL =high], normal creatine kinase [103 IU/L, range = (24 - 250), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 568) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [WITNESSED SUDDEN CADIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 18) the subject experienced sudden cardiac death [witnessed sudden cadiac death] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 17 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low alkaline phosphatase [38 U/L, range = (40 - 129)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 18) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 862) the subject experienced death [death nos] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 105 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.5 mg/L, range = (0 - 3)], low thyrotropin [0.16 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [132 U/L, range = (40 - 129)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 670), the subject had the following on-study laboratory test results with results different than baseline:** normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 862) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 218) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 93 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.54 mg/L, range = (0 - 3)], high erythrocytes [6-8 /HPF, range = 0-8], high alkaline phosphatase [109 U/L, range = (35 - 104)], high bilirubin [1+, range = NEGATIVE], high glucose [1+, range = NEGATIVE], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 172), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [32 g/L, range = (35 - 52), BL =normal], low creatinine [29 umol/L, range = (44 - 80), BL =normal], normal potassium [4 mmol/L, range = (3.3 - 5.1), BL =high], and low protein [57 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 218) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 204) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 28 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, analgesic or antipyretic agent, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 176), the subject had the following on-study laboratory test results with results different than baseline:** high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 204) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 642) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 47 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.3 mg/L, range = (0 - 3)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and low platelets [109 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.5 mmol/L, range = (4.6 - 6.4), BL =normal], and normal platelets [182 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 642) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH UNEXPLAINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 556) the subject experienced death [death unexplained] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 45 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.76 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 511), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 556) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 710) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 37 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.64 mg/L, range = (0 - 3)], high glucose [7.2 mmol/L, range = (4.6 - 6.4)], high bilirubin [1+, range = NEGATIVE], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high calcium [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], normal glucose [5.6 mmol/L, range = (4.6 - 6.4), BL =high], high leukocytes [13-30 /HPF, range = 0-3, BL =normal], and high occult blood [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 710) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 312) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [4.96 mU/L, range = (0.55 - 4.78)], high aspartate aminotransferase [48 U/L, range = (4 - 37)], high creatinine [117 umol/L, range = (62 - 106)], low glucose [4.1 mmol/L, range = (4.6 - 6.4)], low hemoglobin [129 g/L, range = (130 - 177)], high lactate dehydrogenase [292 U/L, range = (5 - 250)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [30 U/L, range = (4 - 37), BL =high], low erythrocytes [3.4 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5), BL =normal], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 312) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE [INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 135) the subject experienced infective exacerbation of chronic obstructive airways disease (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 36 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the infective exacerbation of chronic obstructive airways disease and up to 30 days prior to event onset included: augumentin (active ingredients: amoxicillinum, acidum clavulanicum), cipronex, tazocin, and tienam.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 135) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 546) the subject experienced cardiac failure [heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high creatinine [130 umol/L, range = (62 - 106)], high occult blood [trace, range = NEGATIVE], and high urate [535 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.7 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [252 U/L, range = (5 - 250), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], low platelets [128 10^9/L, range = (140 - 450), BL =normal], and normal urate [399 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 546) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 407) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and other medically important serious event. The event occurred 168 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.54 mg/L, range = (0 - 3)], high glucose [7.3 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 407) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): COLON NEOPLASM [CAECUM TUMOR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 572) the subject experienced colon neoplasm [caecum tumor] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 165 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.39 mU/L, range = (0.55 - 4.78)], high creatine kinase [263 IU/L, range = (24 - 160)], high creatinine [86 umol/L, range = (44 - 80)], low glucose [4.1 mmol/L, range = (4.6 - 6.4)], and high urate [399 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [20.35 mg/L, range = (0 - 3), BL =normal], normal creatine kinase [149 IU/L, range = (24 - 160), BL =high], normal glucose [5.2 mmol/L, range = (4.6 - 6.4), BL =low], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 572) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 919) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 74 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, augmentin, biseptol, ceftazidime, fenofibrate, metronidazolum, and zinnat.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 845), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [12.67 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [161 umol/L, range = (62 - 106), BL =normal], low glucose [4.4 mmol/L, range = (4.6 - 6.4), BL =normal], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to statin. The event ended on PPD (Day 919) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 494) the subject experienced chronic kidney disease [exacerbation of chronic kidney disease] (Grade 4) and on PPD (Day 541) the subject died. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 120 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [45 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [138 U/L, range = (40 - 129)], high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high creatinine [122 umol/L, range = (62 - 106)], high glucose [10.4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 340), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [127 U/L, range = (40 - 129), BL =high], normal creatinine [106 umol/L, range = (62 - 106), BL =high], low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], normal glucose [6.4 mmol/L, range = (4.6 - 6.4), BL =high], low hemoglobin [120 g/L, range = (130 - 177), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], low magnesium [0.6 mmol/L, range = (0.65 - 1.05), BL =normal], and high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 541) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 308) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 69 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and cipronex.

The subject had the following abnormal laboratory test results at baseline: low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], and low hemoglobin [129 g/L, range = (130 - 175)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal hemoglobin [130 g/L, range = (130 - 175), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 308) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 29) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 28 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: low platelets [133 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 29) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 555) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 302 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline: high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 555) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): NEOPLASM [NEOPLASM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 169) the subject experienced neoplasm (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 137 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the neoplasm and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.57 mg/L, range = (0 - 3)], low erythrocytes [4 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [123 g/L, range = (130 - 175)], and low platelets [127 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 169) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Pancreatic)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 734) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 65 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: duomox (amoxicillin).

The subject had the following abnormal laboratory test results at baseline: high CRP [3.9 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high creatinine [108 umol/L, range = (44 - 80)], low glucose [4.1 mmol/L, range = (4.6 - 6.4)], and high urate [345 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 669), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.67 mmol/L, range = (2.86 - 8.21), BL =normal], and normal glucose [4.6 mmol/L, range = (4.6 - 6.4), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 734) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH UNEXPLAINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 303) the subject experienced death [death unexplained] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 47 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [10.7 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 164), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], and normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 303) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): NEOPLASM [NEOPLASM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 662) the subject experienced neoplasm (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 87 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the neoplasm and up to 30 days prior to event onset included: atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 501), the subject had the following on-study laboratory test results with results different than baseline: high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 662) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 628) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 32 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, detreomycyna (chloramphenicol), gardimax medica (chlorhexidine + lidocaine), and taromentin (amoxicillin + clavulanic acid).

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline: high protein [trace, range = NEGATIVE, BL =normal], and high urate [428 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 628) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH (UNKNOWN REASON)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 141) the subject experienced death [death (unknown reason)] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 128 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.95 mg/L, range = (0 - 3)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], high hematocrit [0.53 fraction of 1, range = (0.33 - 0.46)], high hemoglobin [169 g/L, range = (110 - 161)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high protein [2+, range = NEGATIVE], and high urate [452 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 83), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21), BL =normal], normal magnesium [0.75 mmol/L, range = (0.65 - 1.05), BL =low], and high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal].

Action taken with IP and statin was not reported.The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 141) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 124) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 39 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 124) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 227) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 194 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [25.8 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [36 mL/min/1.73m2, range = (60 - 9999)], high creatinine [120 umol/L, range = (44 - 80)], high glucose [10.5 mmol/L, range = (4.6 - 6.4)], high glucose [1+, range = NEGATIVE], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high protein [3+, range = NEGATIVE], and high urate [375 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be related to IP and related to statin. The event ended on PPD (Day 227) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 60) the subject experienced cardiac failure [heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 28 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, beta blocker, and clopidogrel.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 60) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 323) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 172), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [357 IU/L, range = (24 - 250), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and high urate [422 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 323) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 21) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [12.59 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], low platelets [132 10^9/L, range = (140 - 450)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 21) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): COLON CANCER METASTATIC [COLON CANCER METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 784) the subject experienced colon cancer metastatic (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 164 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the colon cancer metastatic and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [22.98 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], low platelets [139 10^9/L, range = (140 - 450)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [140 U/L, range = (40 - 129), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], low hemoglobin [129 g/L, range = (130 - 177), BL =normal], and normal platelets [180 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 784) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOPULMONARY FAILURE [DEATH DUE TO CARDIO-RESPIRATORY INSUFFICIENCY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 423) the subject experienced cardiopulmonary failure [death due to cardio-respiratory insufficiency]. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 101 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiopulmonary failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.54 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.45 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [114 U/L, range = (35 - 104)], high blood urea nitrogen [14.64 mmol/L, range = (2.86 - 8.21)], high creatinine [109 umol/L, range = (44 - 80)], low glucose [4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [285 U/L, range = (5 - 250)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high potassium [5.7 mmol/L, range = (3.3 - 5.1)], high protein [2+, range = NEGATIVE], high sodium [148 mmol/L, range = (135 - 147)], and high urate [494 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [98 U/L, range = (35 - 104), BL =high], high glucose [9.7 mmol/L, range = (4.6 - 6.4), BL =low], normal lactate dehydrogenase [243 U/L, range = (5 - 250), BL =high], high occult blood [1+, range = NEGATIVE, BL =normal], and normal sodium [143 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 423) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [DEATH DUE TO STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 48) the subject experienced cerebrovascular accident [death due to stroke] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.46 mg/L, range = (0 - 3)], high creatine kinase [235 IU/L, range = (20 - 203)], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 48) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PANCREATIC CARCINOMA [PANCREAS CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 219) the subject experienced pancreatic carcinoma [malignant tumor in head of pancreas] (Grade 3) and on PPD (Day 381) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 184 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pancreatic carcinoma and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.32 mg/L, range = (0 - 3)], high erythrocytes [9-14 /HPF, range = 0-5], low creatine kinase [14 IU/L, range = (20 - 203)], high glucose [14.7 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 183), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [134 U/L, range = (40 - 129), BL =normal], low creatinine [50 umol/L, range = (62 - 106), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], low magnesium [0.55 mmol/L, range = (0.65 - 1.05), BL =normal], high occult blood [3+, range = NEGATIVE, BL =normal], high protein [1+, range = NEGATIVE, BL =normal], and low protein [57 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 381) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PANCREATIC CARCINOMA [PANCREATIC CANCER NON-RESECTABLE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 996) the subject experienced pancreatic carcinoma [pancreatic cancer non-resectable] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 15 days after the last dose of any study medication.

Concomitant medications taken at the onset of the pancreatic carcinoma and up to 30 days prior to event onset included: atorvastatin, metronidazol, nifuroksazyd, and tartriakson.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [6-8 /HPF, range = 0-8], low glomerular filtration rate estimated [52 mL/min/1.73m2, range = (60 - 9999)], high creatine kinase [174 IU/L, range = (24 - 160)], high glucose [10.2 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], and high urate [541 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 840), the subject had the following on-study laboratory test results with results different than baseline:** normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 996) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 647) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 55 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: amoksiklav 0.625, atorvastatin, biofazolin, and metronidazol.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.47 mU/L, range = (0.55 - 4.78)], and high creatinine [83 umol/L, range = (44 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 592), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21), BL =normal], high calcium [2.65 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55), BL =normal], low glucose [4.3 mmol/L, range = (4.6 - 6.4), BL =normal], and high hematocrit [0.47 fraction of 1, range = (0.33 - 0.46), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 647) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ANGINA PECTORIS [CHEST PAIN - CARDIAC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 122) the subject experienced angina pectoris [chest pain - cardiac] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the angina pectoris and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.3 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and low magnesium [0.55 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** low platelets [136 10^9/L, range = (140 - 450), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 122) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 785) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 28 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high protein [trace, range = NEGATIVE], high glucose [9.5 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [108 umol/L, range = (62 - 106), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [1+, range = NEGATIVE, BL =normal], and low magnesium [0.62 mmol/L, range = (0.65 - 1.05), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 785) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Pulmonary Embolism)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 344) the subject experienced pulmonary congestion (Grade 4) and on PPD (Day 344) the subject died due to pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 93 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.03 mg/L, range = (0 - 3)], high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], and high glucose [6 mmol/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 344) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): INFLUENZA [INFLUENZA A VIRUS INFECTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 840) the subject experienced influenza [influenza a virus infection] (Grade 4) and on PPD (Day 844) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the influenza and up to 30 days prior to event onset included: acetylsalicylic acid, analgesic or antipyretic agent, angiotensin receptor blocker, antidepressants, atorvastatin, beta blocker, cefuroksym, duomox, fromilid uno, glycemic control medication, insulin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.56 mg/L, range = (0 - 3)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [263 U/L, range = (5 - 250)], and high urate [387 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 675), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [185 IU/L, range = (24 - 160), BL =normal], high glucose [7.8 mmol/L, range = (4.6 - 6.4), BL =normal], normal lactate dehydrogenase [226 U/L, range = (5 - 250), BL =high], and normal urate [321 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 844) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 81) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4) and on PPD (Day 288) the subject died due to the event. The event was considered serious for the following reasons: results in death. The event occurred 208 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: atorvastatin, and taromentin.

The subject had the following abnormal laboratory test results at baseline: high CRP [26.94 mg/L, range = (0 - 3)], high alkaline phosphatase [172 U/L, range = (40 - 129)], high aspartate aminotransferase [43 U/L, range = (4 - 37)], high bilirubin [1+, range = NEGATIVE], low erythrocytes [3.7 10^12/L, range = (4 - 5.8)], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [118 g/L, range = (130 - 177)], high lactate dehydrogenase [252 U/L, range = (5 - 250)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 80), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], high calcium [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], and high urate [452 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 288) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ADENOCARCINOMA OF COLON [ADENOCARCINOMA OF COLON STAGE IV]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 800) the subject experienced adenocarcinoma of colon [adenocarcinoma of colon stage iv] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 799 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the adenocarcinoma of colon and up to 30 days prior to event onset included: atorvastatin, biofazolin, biotrakson, duomox, metronidazol, and metronidazole.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.32 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], low hematocrit [0.32 fraction of 1, range = (0.35 - 0.47)], low hemoglobin [95 g/L, range = (116 - 162)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 680), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], normal blood urea nitrogen [4.14 mmol/L, range = (2.86 - 8.21), BL =high], normal hematocrit [0.36 fraction of 1, range = (0.35 - 0.47), BL =low], and normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 800) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA AGGRAVATED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 767) the subject experienced pneumonia [pneumonia aggravated] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 67 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [42 U/L, range = (4 - 37)], low creatinine [54 umol/L, range = (62 - 106)], high glucose [8.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and low platelets [97 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 681), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [44 U/L, range = (4 - 41), BL =normal], low albumin [30 g/L, range = (35 - 52), BL =normal], high bilirubin [29 umol/L, range = (3 - 21), BL =normal], low calcium [2.13 mmol/L, range = (2.2 - 2.55), BL =normal], high creatine kinase [352 IU/L, range = (20 - 203), BL =normal], high creatinine [118 umol/L, range = (62 - 106), BL =low], high direct bilirubin [16 umol/L, range = (0 - 5), BL =normal], normal glucose [5.5 mmol/L, range = (4.6 - 6.4), BL =high], high lactate dehydrogenase [316 U/L, range = (5 - 250), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 767) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 421) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], low platelets [112 10^9/L, range = (140 - 450)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [268 U/L, range = (5 - 250), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 421) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 66) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 38 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.02 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 66) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 718) the subject experienced death. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 281 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.56 mg/L, range = (0 - 3)], and high glucose [6.5 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], normal glucose [6.3 mmol/L, range = (4.6 - 6.4), BL =high], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 718) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 964) the subject experienced lung neoplasm malignant [lung malignant tumor] (Grade 3) and on PPD (Day 977) the subject died due to the event. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [28.62 mg/L, range = (0 - 3)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [202 U/L, range = (40 - 129), BL =normal], high blood urea nitrogen [8.46 mmol/L, range = (2.86 - 8.21), BL =normal], high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], and high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 977) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SMALL CELL LUNG CANCER [SMALL CELL LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 712) the subject experienced small cell lung cancer [small cell carcinoma of lung] (Grade 3) and on PPD (Day 1052) the subject died due to the event. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 57 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the small cell lung cancer and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [47 U/L, range = (4 - 41)], and high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 841), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [20 U/L, range = (4 - 41), BL =high], low erythrocytes [3.6 10^12/L, range = (4.1 - 5.9), BL =normal], high glucose [6 mmol/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52), BL =normal], and low hemoglobin [125 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1052) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GASTROINTESTINAL HAEMORRHAGE [GI TRACT BLEED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Non-Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 179) the subject experienced gastrointestinal haemorrhage [gi tract bleed] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 24 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastrointestinal haemorrhage and up to 30 days prior to event onset included: analgesic or antipyretic agent, atorvastatin, and enoxaparin.

The subject had the following abnormal laboratory test results at baseline: high CRP [50.35 mg/L, range = (0 - 3)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 174), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [26 g/L, range = (35 - 52), BL =normal], low bilirubin [2 umol/L, range = (3 - 21), BL =normal], low erythrocytes [2.9 10^12/L, range = (4.1 - 5.9), BL =normal], low glucose [4.2 mmol/L, range = (4.6 - 6.4), BL =normal], low hematocrit [0.29 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [92 g/L, range = (130 - 175), BL =normal], high protein [1+, range = NEGATIVE, BL =normal], normal urate [291 umol/L, range = (202 - 416), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 179) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 410) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.02 mg/L, range = (0 - 3)], high alanine aminotransferase [50 U/L, range = (4 - 41)], high glucose [6.2 mmol/L, range = (4.1 - 5.9)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal urate [291 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 410) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): COLON CANCER [COLON CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 381) the subject experienced colon cancer (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the colon cancer and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [10.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high urate [523 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [68 U/L, range = (4 - 41), BL =normal], low albumin [34 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [646 U/L, range = (40 - 129), BL =normal], high aspartate aminotransferase [88 U/L, range = (4 - 37), BL =normal], high CRP [112.54 mg/L, range = (0 - 3), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], low erythrocytes [3.9 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.32 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [98 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [503 U/L, range = (5 - 250), BL =normal], high leukocytes [13.3 10^9/L, range = (4.1 - 12.3), BL =normal], high platelets [474 10^9/L, range = (140 - 450), BL =normal], and normal urate [399 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 381) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 487) the subject experienced pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 10 days after the last dose of any study medication.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin, ezetimibe, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: low bilirubin [2 umol/L, range = (3 - 21)], and low platelets [135 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [8 umol/L, range = (3 - 21), BL =low], high CRP [12.1 mg/L, range = (0 - 3), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 487) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): BRONCHIAL CARCINOMA [CANCER OF BRONCHUS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 269) the subject experienced bronchial carcinoma [cancer of bronchus] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 11 days after the last dose of any study medication.

Concomitant medications taken at the onset of the bronchial carcinoma and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, clopidogrel, ezetimibe, glycemic control medication, insulin, and oral corticosteroids.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 182), the subject had the following on-study laboratory test results with results different than baseline: high alanine aminotransferase [50 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [44 U/L, range = (4 - 37), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 269) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 301) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 18 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and augmentin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high sodium [148 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 176), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high erythrocytes [9-14 /HPF, range = 0-8, BL =normal], normal leukocytes [0-3 /HPF, range = 0-12, BL = missing], high occult blood [trace, range = NEGATIVE, BL =normal], high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal], and normal sodium [144 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 301) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 792) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 595 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, fraxiparin, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.67 mg/L, range = (0 - 3)], high calcium [2.6 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55)], high erythrocytes [9-14 /HPF, range = 0-5], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], high occult blood [2+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.45 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.45 mmol/L, range = (2.2 - 2.55), BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], normal protein [negative, range = NEGATIVE, BL =high], and high urate [470 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 792) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): IDIOPATHIC PULMONARY FIBROSIS [IDIOPATHIC PULMONARY FIBROSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 691) the subject experienced idiopathic pulmonary fibrosis (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 75 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the idiopathic pulmonary fibrosis and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, cipronex (ciprofloxacinum), fortum, and oral corticosteroids.

The subject had the following abnormal laboratory test results at baseline: low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], and low hemoglobin [118 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [4 10^12/L, range = (4 - 5.8), BL =low], normal hematocrit [0.39 fraction of 1, range = (0.37 - 0.5), BL =low], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 691) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PANCREATITIS NECROTISING [DEATH DUE TO ACUTE NECROTIZING PANCREATITIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pancreatic)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 119) the subject experienced pancreatitis necrotising [acute necrotizing pancreatitis] (Grade 4) and on PPD (Day 139) he died. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 110 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pancreatitis necrotising and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 139) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): RENAL CANCER [MALIGNANT NEOPLASM OF LEFT KIDNEY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 975) the subject experienced renal cancer [malignant neoplasm of left kidney] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 79 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the renal cancer and up to 30 days prior to event onset included: atorvastatin, and levofloxacinum.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline: high alkaline phosphatase [136 U/L, range = (40 - 129), BL =normal], low creatinine [61 umol/L, range = (62 - 106), BL =normal], high erythrocytes [9-14 /HPF, range = 0-5, BL =normal], high lactate dehydrogenase [458 U/L, range = (5 - 250), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high occult blood [2+, range = NEGATIVE, BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 975) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 468) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.8 mmol/L, range = (4.6 - 6.4)], low hemoglobin [126 g/L, range = (130 - 177)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [246 IU/L, range = (20 - 203), BL =normal], normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high], and normal hemoglobin [130 g/L, range = (130 - 177), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 468) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): NEOPLASM [TUMOR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 661) the subject experienced neoplasm [tumor] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 100 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the neoplasm and up to 30 days prior to event onset included: amoxicillinum, acidum clavulanicum, atorvastatin, cefazolinum, ciprofloxacinum, clindamycinum, gentamicini sulfas, and vancomicina.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 501), the subject had the following on-study laboratory test results with results different than baseline: low creatine kinase [20 IU/L, range = (24 - 250), BL =normal], low erythrocytes [3.6 10^12/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.31 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [93 g/L, range = (130 - 175), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and high urate [446 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 661) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): NON-SMALL CELL LUNG CANCER [NON SMALL CELL CARCINOMA OF THE LEFT LUNG]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 681) the subject experienced non-small cell lung cancer [non small cell carcinoma of the left lung] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 120 days after the last dose of any study medication.

Concomitant medications taken at the onset of the non-small cell lung cancer and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high creatinine [87 umol/L, range = (44 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [7.4 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 681) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 489) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [44 U/L, range = (4 - 41)], high creatine kinase [258 IU/L, range = (24 - 250)], high creatinine [118 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 339), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [36 U/L, range = (4 - 41), BL =high], normal creatine kinase [151 IU/L, range = (24 - 250), BL =high], normal creatinine [97 umol/L, range = (62 - 106), BL =high], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 489) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): AORTIC ANEURYSM RUPTURE [AORTIC ANEURYSM RUPTURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 452) the subject experienced aortic aneurysm rupture (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the aortic aneurysm rupture and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.43 mg/L, range = (0 - 3)], low thyrotropin [0.25 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [109 umol/L, range = (62 - 106)], low platelets [136 10^9/L, range = (140 - 450)], high protein [trace, range = NEGATIVE], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.5 mmol/L, range = (2.86 - 8.21), BL =high], normal creatinine [102 umol/L, range = (62 - 106), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 452) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 634) the subject experienced cerebrovascular accident [stroke]. The event was considered serious for the following reasons: results in death. The event occurred 311 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.82 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [44 U/L, range = (4 - 41), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 634) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 559) the subject experienced pneumonia (Grade 4) and on PPD (Day 572) the subject died. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 17 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high creatinine [118 umol/L, range = (62 - 106)], low platelets [124 10^9/L, range = (140 - 450)], and high urate [482 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 499), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [184 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [115 U/L, range = (4 - 37), BL =normal], high blood urea nitrogen [10.32 mmol/L, range = (2.86 - 8.21), BL =normal], and normal urate [416 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 572) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 186) the subject experienced pneumonia (Grade 4) and on PPD (Day 194) the subject died. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 20 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, beta blocker, and ciprofloxacine.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.56 mg/L, range = (0 - 3)], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 163), the subject had the following on-study laboratory test results with results different than baseline:** low leukocytes [3.6 10^9/L, range = (4.1 - 12.3), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 194) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 434) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, beta blocker, clopidogrel, rivaroxaban, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [37.94 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], low calcium [1.5 mmol/L, range = (2.2 - 2.55)], low calcium corrected [1.5 mmol/L, range = (2.2 - 2.55)], high creatine kinase [308 IU/L, range = (20 - 203)], high creatinine [109 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [112 g/L, range = (130 - 177)], high lactate dehydrogenase [298 U/L, range = (5 - 250)], high leukocytes [12.4 10^9/L, range = (4.1 - 12.3)], high platelets [456 10^9/L, range = (140 - 450)], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 351), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [6.4 mmol/L, range = (4.6 - 6.4), BL =high], low magnesium [0.58 mmol/L, range = (0.65 - 1.05), BL =normal], and normal urate [410 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 434) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): VENTRICULAR ARRHYTHMIA [VENTRICULAR ARRHYTHMIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 701) the subject experienced ventricular arrhythmia (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 27 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the ventricular arrhythmia and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, amikacin, analgesic or antipyretic agent, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.99 mg/L, range = (0 - 3)], high alkaline phosphatase [131 U/L, range = (40 - 129)], high glucose [13.9 mmol/L, range = (4.6 - 6.4)], high glucose [1+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high occult blood [1+, range = NEGATIVE], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 512), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [129 U/L, range = (40 - 129), BL =high], low bilirubin [<2 umol/L, BL =normal], high blood urea nitrogen [14.99 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [151 umol/L, range = (62 - 106), BL =normal], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [121 g/L, range = (130 - 175), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high], and high urate [482 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 701) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ADENOCARCINOMA GASTRIC [ADENOCARCINOMA GASTRIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 77) the subject experienced adenocarcinoma gastric (Grade 3). On PPD (Day 775) the subject died due to adenocarcinoma gastric (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 688 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the adenocarcinoma gastric and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [26 umol/L, range = (3 - 21)], high direct bilirubin [7 umol/L, range = (0 - 5)], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 513), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [17 umol/L, range = (3 - 21), BL =high], low creatinine [58 umol/L, range = (62 - 106), BL =normal], normal direct bilirubin [5 umol/L, range = (0 - 5), BL =high], normal glucose [5.8 mmol/L, range = (4.6 - 6.4), BL =high], low protein [58 g/L, range = (60 - 80), BL =normal], and normal urate [291 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 775) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PROSTATE CANCER [ADENOCARCINOMA OF PROSTATE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD the subject was diagnosed with prostate cancer. On PPD (Day 236) the subject experienced multiple organ dysfunction syndrome [multiple organ failure] (Grade 4) and on PPD (Day 240) the subject died due to prostate cancer [adenocarcinoma of prostate] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and requires or prolongs hospitalization. The event occurred 169 days after the last dose of any study medication.

Concomitant medications taken at the onset of the prostate cancer and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high calcium [2.73 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.73 mmol/L, range = (2.2 - 2.55)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 175), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], high lactate dehydrogenase [296 U/L, range = (5 - 250), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high occult blood [3+, range = NEGATIVE, BL =normal], high protein [1+, range = NEGATIVE, BL =normal], and normal urate [375 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 240) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG CARCINOMA CELL TYPE UNSPECIFIED STAGE IV [CANCER OF LUNG CELL TYPE UNSPECIFIED STAGE IV]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 477) the subject experienced lung carcinoma cell type unspecified stage iv [cancer of lung cell type unspecified stage iv] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 126 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung carcinoma cell type unspecified stage iv and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low platelets [109 10^9/L, range = (140 - 450)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high], and normal urate [410 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 477) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 569) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 78 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [32.36 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [35 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [162 umol/L, range = (62 - 106)], high erythrocytes [15-30 /HPF, range = 0-5], high leukocytes [tntc /HPF, range = 0-3], high occult blood [3+, range = NEGATIVE], high protein [2+, range = NEGATIVE], and high urate [506 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [7.4 mmol/L, range = (4.6 - 6.4), BL =normal], and low hemoglobin [124 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 569) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE RESPIRATORY FAILURE [ACUTE RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 784) the subject experienced acute respiratory failure (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 34 days after the last dose of any study medication.

Concomitant medications taken at the onset of the acute respiratory failure and up to 30 days prior to event onset included: metronidazol (metronidazolum, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [12.36 mg/L, range = (0 - 3)], low thyrotropin [0.09 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [122 U/L, range = (35 - 104)], low hemoglobin [112 g/L, range = (116 - 162)], high leukocytes [31-50 /HPF, range = 0-12], and high occult blood [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 708), the subject had the following on-study laboratory test results with results different than baseline:** low blood urea nitrogen [2.14 mmol/L, range = (2.86 - 8.21), BL =normal], normal hemoglobin [127 g/L, range = (110 - 161), BL =low], normal leukocytes [0-3 /HPF, range = 0-12, BL =high], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 784) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 566) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 229 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline: low blood urea nitrogen [2.5 mmol/L, range = (2.86 - 8.21), BL =normal], low erythrocytes [4 10^12/L, range = (4.1 - 5.9), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 566) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 564) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 58 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [124 umol/L, range = (62 - 106)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [80 umol/L, range = (62 - 106), BL =high], and normal leukocytes [0-3 /HPF, range = 0-3, BL =high].

The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 564) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE RESPIRATORY FAILURE [ACUTE RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 96) the subject experienced acute respiratory failure (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 67 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute respiratory failure and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.62 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high creatinine [107 umol/L, range = (62 - 106)], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [112 g/L, range = (130 - 177)], high occult blood [trace, range = NEGATIVE], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 96) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 633) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 58 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ceftriaxone.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline: high glucose [6.2 mmol/L, range = (4.1 - 5.9), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 633) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BLADDER ADENOCARCINOMA RECURRENT [BLADDER ADENOCARCINOMA RECURRENT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 593) the subject experienced bladder adenocarcinoma recurrent (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the bladder adenocarcinoma recurrent and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, fenofibrate, glycemic control medication, insulin, rosuvastatin, and the patient didn't know precise the antibiotic name but by the posology it seems that the patient did azithromycin..

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [36 U/L, range = (40 - 129)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [151 umol/L, range = (62 - 106)], low hemoglobin [128 g/L, range = (130 - 177)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [44 U/L, range = (40 - 129), BL =low], high glucose [7.2 mmol/L, range = (4.6 - 6.4), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 593) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [FOUND DEAD (CAUSE UNDETERMINED)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 241) the subject experienced death [found dead (cause undetermined)] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 211 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.51 mg/L, range = (0 - 3)], and high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 241) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 248) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [10.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], high potassium [5.8 mmol/L, range = (3.3 - 5.1), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 248) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SEPSIS [SEPSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 682) the subject experienced sepsis (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 9 days after the last dose of any study medication.

Concomitant medications taken at the onset of the sepsis and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, amoxiciline + clavulanic acid, analgesic or antipyretic agent, atorvastatin, beta blocker, ceftriaxone, cefuroxime, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [173 U/L, range = (40 - 129)], high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high creatinine [147 umol/L, range = (62 - 106)], high glucose [7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], and high urate [494 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [114 U/L, range = (40 - 129), BL =high], high creatine kinase [296 IU/L, range = (20 - 203), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high lactate dehydrogenase [293 U/L, range = (5 - 250), BL =normal], high leukocytes [tntc /HPF, range = 0-3, BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and high protein [83 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 682) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): RUPTURED CEREBRAL ANEURYSM [RUPTURED CEREBRAL ANEURYSM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 765) the subject experienced ruptured cerebral aneurysm (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 92 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the ruptured cerebral aneurysm and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [395 IU/L, range = (20 - 203)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], low hemoglobin [122 g/L, range = (130 - 177)], low leukocytes [3.4 10^9/L, range = (4.1 - 12.3)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [194 IU/L, range = (20 - 203), BL =high], high protein [trace, range = NEGATIVE, BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 765) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 440) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: low creatinine [61 umol/L, range = (62 - 106)], high glucose [16.4 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and low platelets [122 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [38 U/L, range = (4 - 37), BL =normal], normal creatinine [68 umol/L, range = (62 - 106), BL =low], low glucose [4.1 mmol/L, range = (4.6 - 6.4), BL =high], and normal glucose [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 440) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): HAEMORRHAGIC STROKE [HEMORRHAGIC STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 261) the subject experienced haemorrhagic stroke [hemorrhagic stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the haemorrhagic stroke and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.62 mg/L, range = (0 - 3)], low alkaline phosphatase [38 U/L, range = (40 - 129)], high blood urea nitrogen [10 mmol/L, range = (2.14 - 7.14)], high calcium [2.63 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58)], high protein [trace, range = NEGATIVE], and high urate [601 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [43 U/L, range = (40 - 129), BL =low], normal blood urea nitrogen [6.78 mmol/L, range = (2.14 - 7.14), BL =high], normal calcium [2.55 mmol/L, range = (2.1 - 2.58), BL =high], and normal calcium corrected [2.55 mmol/L, range = (2.1 - 2.58), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 261) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 529) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 178 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ezetimibe, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5)], and high urate [535 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 342), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [6.47 mg/L, range = (0 - 3), BL =normal], normal hematocrit [0.46 fraction of 1, range = (0.37 - 0.5), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 529) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 555) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 231 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acenocoumerol, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [14.97 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high protein [2+, range = NEGATIVE], and high protein [82 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal blood urea nitrogen [7.5 mmol/L, range = (2.86 - 8.21), BL =high], normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high], and normal protein [72 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 555) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 803) the subject experienced cardiac arrest. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: high glucose [9.8 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [121 g/L, range = (130 - 175)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 670), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.1 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [114 umol/L, range = (62 - 106), BL =normal], normal hematocrit [0.44 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [142 g/L, range = (130 - 175), BL =low], high leukocytes [17 10^9/L, range = (4.1 - 12.3), BL =normal], high potassium [6 mmol/L, range = (3.3 - 5.1), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], high urate [446 umol/L, range = (202 - 416), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 803) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): HEPATIC CIRRHOSIS [CIRRHOSIS OF LIVER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Hepatobiliary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 599) the subject experienced hepatic cirrhosis [cirrhosis of liver] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. On PPD the subject was hospitalized with jaundice and was diagnosed with decompensated post-viral (hepatitis C) liver cirrhosis, which was likely triggered by cytostatic chemotherapy for non-Hodgkin's lymphoma. On PPD PPD the subject died. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the hepatic cirrhosis and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, ampicillinum, atorvastatin, beta blocker, and glycemic control medication.

Date	Visit	Relative Day	AST range 4-37 U/L	ALT range 4-41 U/L	ALP range 40-129 U/L	T. Bili range 3-21 umol/L
PPD	DAY 1	1	38	55	59	12
	WEEK 12	86	30	34	55	12
	WEEK 24	171	39	51	60	10
	WEEK 48	339	30	44	59	15

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 599) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [BRONCHOPNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD
PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 724) the subject experienced pneumonia [bronchopneumonia]. The event was considered serious for the following reasons: results in death. The event occurred 9 days after the last dose of any study medication.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin, and augmentin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.37 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [35 U/L, range = (40 - 129)], high blood urea nitrogen [11.42 mmol/L, range = (2.86 - 8.21)], high creatine kinase [278 IU/L, range = (20 - 203)], high creatinine [155 umol/L, range = (62 - 106)], low glucose [4.4 mmol/L, range = (4.6 - 6.4)], high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5)], and high potassium [5.3 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [41 U/L, range = (40 - 129), BL =low], normal creatine kinase [74 IU/L, range = (20 - 203), BL =high], normal glucose [4.7 mmol/L, range = (4.6 - 6.4), BL =low], and normal potassium [4.8 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 724) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 57) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 28 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, apixaban, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [33 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [14.64 mmol/L, range = (2.86 - 8.21)], high creatinine [141 umol/L, range = (44 - 80)], low hematocrit [0.3 fraction of 1, range = (0.33 - 0.46)], low hemoglobin [92 g/L, range = (110 - 161)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high potassium [>7.0 mmol/L], and high urate [404 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 57) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [DEATH - CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 151) the subject experienced cardiovascular disorder [death - cardiovascular] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 150 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [10.6 mmol/L, range = (4.6 - 6.4)], low hemoglobin [119 g/L, range = (130 - 177)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [139 U/L, range = (40 - 129), BL =normal], low erythrocytes [3.5 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.31 fraction of 1, range = (0.37 - 0.5), BL =normal], and high urate [535 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 151) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 24) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 23 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, atorvastatin, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [34.03 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [6.06 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high creatinine [156 umol/L, range = (62 - 106)], low hemoglobin [129 g/L, range = (130 - 177)], high potassium [5.9 mmol/L, range = (3.3 - 5.1)], and high protein [83 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 24) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 467) the subject experienced death [unknown cause of death]. The event was considered serious for the following reasons: results in death. The event occurred 158 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [11.7 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high potassium [5.6 mmol/L, range = (3.3 - 5.1)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 332), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], low calcium [1.93 mmol/L, range = (2.1 - 2.58), BL =normal], low calcium corrected [2 mmol/L, range = (2.1 - 2.58), BL =normal], high direct bilirubin [9 umol/L, range = (0 - 5), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [108 g/L, range = (130 - 175), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], low sodium [128 mmol/L, range = (135 - 147), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

Action taken with IP and statin was not reported.The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 467) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Hepatobiliary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 845) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 16 days after the last dose of any study medication. No treatment medications were reported for the event.

On PPD , the subject presented at the scheduled site visit and reported that he had abdominal pain (predominantly in the superior abdominal region) for three days. The pain increased with physical effort with absence of bowel movement. Scleral jaundice, leg edema and distended abdomen were noted. There were no signs of peritoneal irritation or acute abdomen. Hospitalization was recommended for additional investigations, however the subject refused. On PPD , a relative of the subject informed the site that the subject had sudden loss of consciousness and died at home. An autopsy was not performed and a death certificate was not available. The investigator reported that a possible etiology for elevation of the event included alcohol use, possible exposure to chemicals (the subject live at countryside), and ischemic liver due to heart failure and mesenteric ischemia.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

Date	Visit	Relative Day	AST range 4-37 U/L	ALT range 4-41 U/L	ALP range 40-129 U/L	T. Bili range 3-21 umol/L
PPD	DAY 1	1	22	29	90	5
	WEEK 12	85	22	24	75	5

PPD	WEEK 24	169	20	24	84	7
	WEEK 48	338	17	24	62	7
	WEEK 72	507	17	18	66	11
	WEEK 96	672	17	35	76	12
	WEEK 120	842	159	185	141	42

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 845) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pancreatic)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 460) the subject experienced pancreatitis acute [acute pancreatitis] (Grade 4) and on PPD (Day 472) the subject experienced death. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 47 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.18 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [108 umol/L, range = (62 - 106), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 472) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 438) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [21 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [22.13 mmol/L, range = (2.86 - 8.21)], high creatinine [301 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9)], low glucose [3.3 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [120 g/L, range = (130 - 175)], high potassium [6.4 mmol/L, range = (3.3 - 5.1)], high protein [3+, range = NEGATIVE], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [6.13 mg/L, range = (0 - 3), BL =normal], normal erythrocytes [4.3 10^12/L, range = (4.1 - 5.9), BL =low], normal hematocrit [0.43 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [130 g/L, range = (130 - 175), BL =low], high leukocytes [14.3 10^9/L, range = (4.1 - 12.3), BL =normal], and high occult blood [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 438) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 645) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 56 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, cefazoline, and ceftriaxone.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], low bilirubin [2 umol/L, range = (3 - 21)], high blood urea nitrogen [16.42 mmol/L, range = (2.14 - 7.14)], high creatinine [208 umol/L, range = (62 - 106)], low erythrocytes [3.4 10^12/L, range = (4.1 - 5.9)], high glucose [18.3 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], low hematocrit [0.31 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [97 g/L, range = (130 - 175)], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [273 U/L, range = (5 - 250)], high occult blood [trace, range = NEGATIVE], high potassium [5.8 mmol/L, range = (3.3 - 5.1)], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [3 umol/L, range = (3 - 21), BL =low], low calcium [1.9 mmol/L, range = (2.1 - 2.58), BL =normal], low calcium corrected [2 mmol/L, range = (2.1 - 2.58), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], and high urate [535 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 645) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Suicide)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 815) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 59 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [40 U/L, range = (4 - 37)], high creatine kinase [264 IU/L, range = (24 - 250)], high lactate dehydrogenase [290 U/L, range = (5 - 250)], high protein [2+, range = NEGATIVE], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 666), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [52 U/L, range = (4 - 41), BL =normal], high alkaline phosphatase [140 U/L, range = (40 - 129), BL =normal], normal aspartate aminotransferase [32 U/L, range = (4 - 37), BL =high], normal creatine kinase [196 IU/L, range = (24 - 250), BL =high], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], normal protein [negative, range = NEGATIVE, BL =high], and high protein [82 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 815) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBRAL INFARCTION [CEREBRAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 464) the subject experienced cerebral infarction (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [24 umol/L, range = (3 - 21)], and low creatinine [59 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [7 umol/L, range = (3 - 21), BL =high], normal creatinine [75 umol/L, range = (62 - 106), BL =low], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [9 mmol/L, range = (4.6 - 6.4), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], high protein [trace, range = NEGATIVE, BL =normal], and high urate [464 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 464) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 193) the subject experienced cardiac failure chronic [heart failure nyha class iii] (Grade 3) and on PPD (Day 202) the subject died. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 37 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [17.14 mmol/L, range = (2.86 - 8.21)], high calcium [2.73 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.73 mmol/L, range = (2.2 - 2.55)], high creatinine [176 umol/L, range = (62 - 106)], high glucose [8.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high potassium [5.6 mmol/L, range = (3.3 - 5.1)], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 165), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [38 U/L, range = (4 - 37), BL =normal], normal blood urea nitrogen [5 mmol/L, range = (2.86 - 8.21), BL =high], normal calcium [2.38 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.38 mmol/L, range = (2.2 - 2.55), BL =high], normal creatinine [69 umol/L, range = (62 - 106), BL =high], normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], normal potassium [4.1 mmol/L, range = (3.3 - 5.1), BL =high], high protein [1+, range = NEGATIVE, BL =normal], and normal urate [321 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 202) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): POISONING [INTOXICATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 674) the subject experienced poisoning [intoxication]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 88 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the poisoning and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, atorvastatin, beta blocker, and rivaroxaban.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [40 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [13.21 mmol/L, range = (2.86 - 8.21)], high CRP [9.38 mg/L, range = (0 - 3)], high creatinine [180 umol/L, range = (62 - 106)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], high sodium [150 mmol/L, range = (135 - 147)], and high urate [517 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 531), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.1 mmol/L, range = (2.86 - 8.21), BL =high], high calcium [2.59 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], normal creatinine [90 umol/L, range = (62 - 106), BL =high], normal potassium [4.1 mmol/L, range = (3.3 - 5.1), BL =high], and normal sodium [145 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 674) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 76) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.87 mg/L, range = (0 - 3)], high glucose [11.1 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], and high protein [82 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 76) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 999) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 832 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.61 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high creatinine [90 umol/L, range = (44 - 80)], and high urate [399 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 351), the subject had the following on-study laboratory test results with results different than baseline:** normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 999) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [DEATH - CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 444) the subject experienced cardiac failure acute [acute heart failure] (Grade 4) and cardiovascular disorder [death - cardiovascular]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, angiotensin receptor blocker, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [314 IU/L, range = (20 - 203)], high erythrocytes [6-8 /HPF, range = 0-5], high glucose [9.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], low platelets [115 10^9/L, range = (140 - 450)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [4.62 mg/L, range = (0 - 3), BL =normal], normal creatine kinase [166 IU/L, range = (20 - 203), BL =high], high glucose [trace, range = NEGATIVE, BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 444) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 358) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [16.69 mg/L, range = (0 - 3)], high alanine aminotransferase [78 U/L, range = (4 - 41)], high aspartate aminotransferase [64 U/L, range = (4 - 37)], high bilirubin [1+, range = NEGATIVE], high creatine kinase [1347 IU/L, range = (20 - 203)], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [254 U/L, range = (5 - 250)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [18 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [17 U/L, range = (4 - 37), BL =high], normal bilirubin [negative, range = NEGATIVE, BL =high], normal creatine kinase [166 IU/L, range = (20 - 203), BL =high], normal glucose [5.8 mmol/L, range = (4.6 - 6.4), BL =high], normal lactate dehydrogenase [176 U/L, range = (5 - 250), BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], normal protein [negative, range = NEGATIVE, BL =high], and high sodium [148 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 358) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 378) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [36 umol/L, range = (3 - 21)], high blood urea nitrogen [12.85 mmol/L, range = (2.86 - 8.21)], high creatine kinase [402 IU/L, range = (20 - 203)], high creatinine [109 umol/L, range = (62 - 106)], high direct bilirubin [7 umol/L, range = (0 - 5)], low hemoglobin [129 g/L, range = (130 - 177)], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.14 mmol/L, range = (2.86 - 8.21), BL =high], normal creatine kinase [141 IU/L, range = (20 - 203), BL =high], normal creatinine [98 umol/L, range = (62 - 106), BL =high], normal direct bilirubin [5 umol/L, range = (0 - 5), BL =high], and normal urate [369 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 378) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CORONARY DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 357) the subject experienced sudden cardiac death [sudden coronary death] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. One month after start of IP the subject experienced a 10 kg weight loss. One month later he developed generalized weakness, muscle cramps, back pain, and voice hoarseness; CPK was normal. IP and atorvastatin were discontinued. The subject's symptoms persisted, and he experienced dyspnea due to weakness of respiratory muscles. Four months after the onset of the generalized weakness, muscle cramps, back pain, and voice hoarseness the subject was diagnosed with ALS. The subject was treated with riluzole and CPAP (continuous positive-airway pressure). The subject had no history of immunologic or chronic inflammatory disease and no history of non stroke-related neurological findings at screening; there was no history of trauma, viral infection, occupational exposure to toxins, nutritional deficiency, or chronic fatigue syndrome, and no relevant family history. On PPD the subject died due to ALS. The event occurred 288 days after the last dose of any study medication.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [50 U/L, range = (4 - 41)], high aspartate aminotransferase [44 U/L, range = (4 - 37)], and high creatine kinase [521 IU/L, range = (20 - 203)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 174), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [24 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [28 U/L, range = (4 - 37), BL =high], high bilirubin [1+, range = NEGATIVE, BL =normal], normal creatine kinase [201 IU/L, range = (20 - 203), BL =high], high hematocrit [0.52 fraction of 1, range = (0.37 - 0.5), BL =normal], high occult blood [trace, range =

NEGATIVE, BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 357) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 617) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 33 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, ceftriaxone, and metrogil.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.33 mg/L, range = (0 - 3)], and low hemoglobin [129 g/L, range = (130 - 175)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal hemoglobin [138 g/L, range = (130 - 177), BL =low], and low platelets [136 10^9/L, range = (140 - 450), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 617) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 243) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [63 U/L, range = (4 - 41)], high aspartate aminotransferase [50 U/L, range = (4 - 37)], high CRP [21.23 mg/L, range = (0 - 3)], high creatinine [112 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high lactate dehydrogenase [254 U/L, range = (5 - 250)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [102 umol/L, range = (62 - 106), BL =high], high glucose [6.9 mmol/L, range = (4.6 - 6.4), BL =normal], normal lactate dehydrogenase [206 U/L, range = (5 - 250), BL =high], and high leukocytes [4-12 /HPF, range = 0-3, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 243) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Pulmonary Embolism)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 712) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 46 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [12.14 mmol/L, range = (2.14 - 7.14)], high creatinine [83 umol/L, range = (44 - 80)], high glucose [9.3 mmol/L, range = (4.1 - 5.9)], and high urate [452 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 666), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [42 U/L, range = (4 - 33), BL =normal], high alkaline phosphatase [208 U/L, range = (35 - 104), BL =normal], high aspartate aminotransferase [34 U/L, range = (4 - 31), BL =normal], high bilirubin [24 umol/L, range = (3 - 21), BL =normal], high creatine kinase [228 IU/L, range = (24 - 170), BL =normal], high direct bilirubin [14 umol/L, range = (0 - 5), BL =normal], low glucose [3 mmol/L, range = (4.6 - 6.4), BL =high], high lactate dehydrogenase [350 U/L, range = (5 - 250), BL =normal], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 712) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CORONARY ARTERY THROMBOSIS [CORONARY THROMBOSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 263) the subject experienced coronary artery thrombosis [coronary thrombosis] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 24 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the coronary artery thrombosis and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and rivaroxaban.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.3 mg/L, range = (0 - 3)], high aspartate aminotransferase [58 U/L, range = (4 - 37)], high blood urea nitrogen [11.42 mmol/L, range = (2.86 - 8.21)], high creatine kinase [910 IU/L, range = (24 - 250)], high lactate dehydrogenase [414 U/L, range = (5 - 250)], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 254), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [13.1 10^9/L, range = (4.1 - 12.3), BL =normal], and normal urate [399 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 263) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [CANCER OF LUNG]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 265) the subject experienced lung neoplasm malignant [peripheral cancer of the right lung] (Grade 4) and on PPD (Day 446) the subject died due to the event. The event was considered serious for the following reasons: results in death. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, and ciprofloxacin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.76 mg/L, range = (0 - 3)], and high urate [523 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 339), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [132 U/L, range = (40 - 129), BL =normal], high leukocytes [13.1 10^9/L, range = (4.1 - 12.3), BL =normal], and normal urate [387 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 446) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1035) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 26 days after the last dose of any study medication.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [14.5 mg/L, range = (0 - 3)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [79 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [41 U/L, range = (4 - 37), BL =normal], high bilirubin [23 umol/L, range = (3 - 21), BL =normal], high glucose [11.7 mmol/L, range = (4.6 - 6.4), BL =normal], and high glucose [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1035) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL FIBROSIS [POSTINFARCTION CARDIOSCLEROSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 329) the subject experienced myocardial fibrosis [postinfarction cardiosclerosis] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial fibrosis and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.62 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [45 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high glucose [6.6 mmol/L, range = (4.1 - 5.9)], high protein [1+, range = NEGATIVE], and high urate [720 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high creatinine [120 umol/L, range = (62 - 106), BL =normal], high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 329) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 630) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 523 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [12.49 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high occult blood [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 107), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [133 U/L, range = (40 - 129), BL =normal], high calcium [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], and high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 630) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 26) the subject experienced sudden death [sudden death, cause unknown] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.38 mg/L, range = (0 - 3)], and low erythrocytes [3.9 10^12/L, range = (4 - 5.8)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 26) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH UNEXPLAINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 143) the subject experienced death [death unexplained] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 57 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [24.01 mg/L, range = (0 - 3)], high leukocytes [4-12 /HPF, range = 0-3], high hematocrit [0.53 fraction of 1, range = (0.37 - 0.5)], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** normal hematocrit [0.49 fraction of 1, range = (0.37 - 0.5), BL =high], and normal urate [375 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 143) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ARTERIOSCLEROSIS [ATEROSCLEROTIC CARDIOSCLEROSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 272) the subject experienced arteriosclerosis [aterosclerotic cardiosclerosis] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 22 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the arteriosclerosis and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [132 U/L, range = (40 - 129)], high aspartate aminotransferase [38 U/L, range = (4 - 37)], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], high CRP [9.61 mg/L, range = (0 - 3)], high lactate dehydrogenase [251 U/L, range = (5 - 250)], and high occult blood [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [27 U/L, range = (4 - 37), BL =high], high bilirubin [32 umol/L, range = (3 - 21), BL =normal], high creatinine [115 umol/L, range = (62 - 106), BL =normal], high direct bilirubin [10 umol/L, range = (0 - 5), BL =normal], normal lactate dehydrogenase [243 U/L, range = (5 - 250), BL =high], high leukocytes [4-12 /HPF, range = 0-3, BL = missing], and high protein [3+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 272) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARBON MONOXIDE POISONING [CARBON MONOXIDE POISONING]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 797) the subject experienced carbon monoxide poisoning. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 47 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the carbon monoxide poisoning and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 670), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.75 mmol/L, range = (2.86 - 8.21), BL =high], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 797) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 165) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 83 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.28 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high lactate dehydrogenase [450 U/L, range = (5 - 250)], high protein [trace, range = NEGATIVE], and high thyrotropin [8.65 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 82), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.7 mmol/L, range = (4.6 - 6.4), BL =normal], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 165) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 300) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 139 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [48.67 mg/L, range = (0 - 3)], high creatinine [116 umol/L, range = (62 - 106)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [120 g/L, range = (130 - 175)], high occult blood [trace, range = NEGATIVE], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 90), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [91 umol/L, range = (62 - 106), BL =high], normal hematocrit [0.42 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [136 g/L, range = (130 - 175), BL =low], and normal potassium [4.7 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 300) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 486) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 65 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.76 mg/L, range = (0 - 3)], high calcium [2.63 mmol/L, range = (2.1 - 2.58)], and high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 365), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [0.96 mg/L, range = (0 - 3), BL =high], normal calcium [2.41 mmol/L, range = (2.1 - 2.58), BL =high], normal calcium corrected [2.4 mmol/L, range = (2.1 - 2.58), BL =high], low glucose [4.2 mmol/L, range = (4.6 - 6.4), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], high occult blood [1+, range = NEGATIVE, BL =normal], high potassium [>7.0 mmol/L, BL =normal], and high urate [482 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 486) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): METASTASES TO CENTRAL NERVOUS SYSTEM [METASTASES TO BRAIN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 133) the subject experienced metastases to central nervous system [metastases to brain] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 70 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the metastases to central nervous system and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [6 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 133) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC DEATH [CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1083) the subject experienced cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 18 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac death and up to 30 days prior to event onset included: atorvastatin, and ceftriaxone.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.61 mg/L, range = (0 - 3)], high aspartate aminotransferase [40 U/L, range = (4 - 37)], high glucose [10.9 mmol/L, range = (4.1 - 5.9)], high glucose [1+, range = NEGATIVE], high hematocrit [0.54 fraction of 1, range = (0.4 - 0.52)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high leukocytes [12.4 10^9/L, range = (4.1 - 12.3)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [14 U/L, range = (4 - 37), BL =high], high urate [428 umol/L, range = (202 - 416), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1083) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 641) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [10.3 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], and high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 502), the subject had the following on-study laboratory test results with results different than baseline:** normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 641) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 440) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.8 mmol/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 330), the subject had the following on-study laboratory test results with results different than baseline:** low alkaline phosphatase [35 U/L, range = (40 - 129), BL =normal], high blood urea nitrogen [7.57 mmol/L, range = (2.14 - 7.14), BL =normal], and high creatine kinase [386 IU/L, range = (24 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 440) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 272) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high glucose [8.3 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], high leukocytes [4-12 /HPF, range = 0-3], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 182), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [118 umol/L, range = (62 - 106), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], high occult blood [trace, range = NEGATIVE, BL =normal], high sodium [148 mmol/L, range = (135 - 147), BL =normal], and high urate [434 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 272) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 514) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 99 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [47 mL/min/1.73m2, range = (60 - 9999)], high creatinine [120 umol/L, range = (62 - 106)], high occult blood [2+, range = NEGATIVE], high protein [1+, range = NEGATIVE], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 345), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high CRP [3.32 mg/L, range = (0 - 3), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [119 g/L, range = (130 - 177), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], and high lactate dehydrogenase [261 U/L, range = (5 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 514) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 672) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 20 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, beta blocker, hormone replacement therapy, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.16 mg/L, range = (0 - 3)], high thyrotropin [4.82 mU/L, range = (0.55 - 4.78)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 666), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], normal blood urea nitrogen [7.1 mmol/L, range = (2.86 - 8.21), BL =high], high creatine kinase [328 IU/L, range = (20 - 203), BL =normal], high creatinine [108 umol/L, range = (62 - 106), BL =normal], low hemoglobin [127 g/L, range = (130 - 177), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and high urate [464 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 672) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 481) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 56 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high creatinine [117 umol/L, range = (62 - 106)], low erythrocytes [3.5 10^12/L, range = (4 - 5.8)], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [108 g/L, range = (130 - 177)], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 341), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21), BL =normal], normal hematocrit [0.37 fraction of 1, range = (0.37 - 0.5), BL =low], low leukocytes [4 10^9/L, range = (4.1 - 12.3), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 481) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): BRAIN OEDEMA [BRAIN EDEMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 942) the subject experienced brain oedema [brain edema] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 689 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the brain oedema and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], and high creatinine [109 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 842), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [84 umol/L, range = (62 - 106), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], high lactate dehydrogenase [277 U/L, range = (5 - 250), BL =normal], high urate [458 umol/L, range = (202 - 416), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 942) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 96) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.17 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.14 mmol/L, range = (2.86 - 8.21), BL =high], and normal urate [369 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 96) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): AORTIC ANEURYSM [ANEURYSM OF THORACIC AORTA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 104) the subject experienced aortic aneurysm [aneurysm of thoracic aorta] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the aortic aneurysm and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.47 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high creatinine [132 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], and low hemoglobin [122 g/L, range = (130 - 175)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.14 - 7.14), BL =normal], normal erythrocytes [4.2 10^12/L, range = (4.1 - 5.9), BL =low], and normal hematocrit [0.4 fraction of 1, range = (0.4 - 0.52), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 104) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 390) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 389 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [24 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high direct bilirubin [7 umol/L, range = (0 - 5)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], high protein [2+, range = NEGATIVE], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 330), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high CRP [7.27 mg/L, range = (0 - 3), BL =normal], high creatinine [206 umol/L, range = (62 - 106), BL =normal], normal glucose [4.6 mmol/L, range = (4.6 - 6.4), BL =high], high lactate dehydrogenase [263 U/L, range = (5 - 250), BL =normal], high magnesium [1.14 mmol/L, range = (0.65 - 1.05), BL =normal], normal potassium [4.7 mmol/L, range = (3.3 - 5.1), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 390) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LYMPHOMA [LYMPHOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 272) the subject experienced lymphoma (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 106 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lymphoma and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.26 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [4.86 mU/L, range = (0.55 - 4.78)], high bilirubin [1+, range = NEGATIVE], high creatine kinase [370 IU/L, range = (24 - 160)], high creatinine [93 umol/L, range = (44 - 80)], high glucose [8.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [39 U/L, range = (4 - 33), BL =normal], high alkaline phosphatase [152 U/L, range = (35 - 104), BL =normal], normal bilirubin [negative, range = NEGATIVE, BL =high], normal creatine kinase [72 IU/L, range = (24 - 160), BL =high], normal creatinine [63 umol/L, range = (44 - 80), BL =high], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and low urate [137 umol/L, range = (143 - 339), BL

=normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 272) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): POISONING [INTOXICATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 532) the subject experienced poisoning [intoxication] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 112 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the poisoning and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.24 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [256 U/L, range = (40 - 129), BL =normal], normal CRP [0.94 mg/L, range = (0 - 3), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 532) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 83) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 42 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 83) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 667) the subject experienced cardiac failure acute [acute heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.86 mg/L, range = (0 - 3)], high glucose [trace, range = NEGATIVE], high protein [trace, range = NEGATIVE], high glucose [11.8 mmol/L, range = (4.1 - 5.9)], and high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 666), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [49 U/L, range = (4 - 41), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 667) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GASTRIC CANCER [STOMACH CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 481) the subject experienced gastric cancer [stomach cancer] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 480 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastric cancer and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high creatine kinase [240 IU/L, range = (20 - 203)], high protein [trace, range = NEGATIVE], and high thyrotropin [5.9 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high CRP [5.73 mg/L, range = (0 - 3), BL =normal], normal creatine kinase [124 IU/L, range = (20 - 203), BL =high], high glucose [7.2 mmol/L, range = (4.6 - 6.4), BL =normal], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 481) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 52) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 14 days after the last dose of any study medication.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.38 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [32 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [165 U/L, range = (35 - 104)], high blood urea nitrogen [13.21 mmol/L, range = (2.86 - 8.21)], high creatinine [145 umol/L, range = (44 - 80)], high glucose [12.5 mmol/L, range = (4.6 - 6.4)], low hemoglobin [113 g/L, range = (116 - 162)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], and high urate [464 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 52) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 358) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.31 mg/L, range = (0 - 3)], high bilirubin [26 umol/L, range = (3 - 21)], high creatine kinase [308 IU/L, range = (24 - 250)], high direct bilirubin [7 umol/L, range = (0 - 5)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 349), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [88 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [50 U/L, range = (4 - 37), BL =normal], normal direct bilirubin [3 umol/L, range = (0 - 5), BL =high], high hematocrit [0.55 fraction of 1, range = (0.4 - 0.52), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 358) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included myocardial PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 399) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and josamycin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.3 mg/L, range = (0 - 3)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 364), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.66 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing], normal potassium [4.8 mmol/L, range = (3.3 - 5.1), BL =high], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 399) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 461) the subject experienced cardiac failure acute [acute heart failure] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.51 mg/L, range = (0 - 3)], low thyrotropin [0.54 mU/L, range = (0.55 - 4.78)], high erythrocytes [tntc /HPF, range = 0-5], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [2+, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [112 umol/L, range = (62 - 106), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 461) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 575) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 545 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 527), the subject had the following on-study laboratory test results with results different than baseline:** normal glomerular filtration rate, estimated [69 mL/min/1.73m2, range = (60 - 9999), BL =low], high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5), BL =normal], and high sodium [148 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 575) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 761) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [26 umol/L, range = (3 - 21)], high glucose [6.9 mmol/L, range = (4.1 - 5.9)], high protein [1+, range = NEGATIVE], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 675), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [45 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [39 U/L, range = (4 - 37), BL =normal], normal bilirubin [21 umol/L, range = (3 - 21), BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 761) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC DEATH [CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 593) the subject experienced cardiac death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac death and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [22.82 mg/L, range = (0 - 3)], high glucose [9.8 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [3+, range = NEGATIVE], and high urate [428 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [23 umol/L, range = (3 - 21), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], high hematocrit [0.51 fraction of 1, range = (0.35 - 0.47), BL =normal], and high sodium [148 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 593) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIOGENIC SHOCK [CARDIOGENIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 87) the subject experienced cardiogenic shock (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 51 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiogenic shock and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.11 mg/L, range = (0 - 3)], high bilirubin [24 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.5)], high lactate dehydrogenase [423 U/L, range = (5 - 250)], high leukocytes [13.7 10^9/L, range = (4.1 - 12.3)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high protein [trace, range = NEGATIVE], and high urate [410 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 87) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: Not applicable

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

On PPD (Day 617) the subject experienced sudden death. The event was considered serious for the following reasons: results in death. The subject was not treated with any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [46 U/L, range = (4 - 37)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatinine [121 umol/L, range = (62 - 106)], and low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 617) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 275) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 275) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 612) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [6.1 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.5 mmol/L, range = (4.6 - 6.4), BL =high], normal hematocrit [0.42 fraction of 1, range = (0.4 - 0.52), BL =low], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 612) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 119) the subject experienced sudden death [sudden death, cause unknown] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 34 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.2 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.7 10^12/L, range = (3.8 - 5.5), BL =normal], low hemoglobin [114 g/L, range = (116 - 162), BL =normal], high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [351 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 119) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 446) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [45 U/L, range = (4 - 41)], and high potassium [5.4 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 335), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [33 U/L, range = (4 - 41), BL =high], normal HbA1c [0.05 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 446) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [DEATH - CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 780) the subject experienced cardiovascular disorder [death - cardiovascular] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [114 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [8.21 mmol/L, range = (2.86 - 8.21), BL =high], normal creatinine [101 umol/L, range = (62 - 106), BL =high], low hemoglobin [121 g/L, range = (130 - 177), BL =normal], and normal urate [333 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 780) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 260) the subject experienced sudden death [sudden death, cause unknown] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.07 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.12 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [11.42 mmol/L, range = (2.86 - 8.21)], high creatinine [128 umol/L, range = (62 - 106)], low hemoglobin [121 g/L, range = (130 - 177)], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], and high urate [666 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 166), the subject had the following on-study laboratory test results with results different than baseline:** low calcium [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], low creatine kinase [18 IU/L, range = (20 - 203), BL =normal], high glucose [7.1 mmol/L, range = (4.6 - 6.4), BL =normal], and normal potassium [4.2 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 260) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 402) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 37 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and sulfacyl-sodium.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [9-14 /HPF, range = 0-8], high glucose [15.8 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high occult blood [2+, range = NEGATIVE], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], high CRP [10.94 mg/L, range = (0 - 3), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 402) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE CORONARY SYNDROME [ACUTE CORONARY SYNDROME]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 345) the subject experienced acute coronary syndrome (Grade 4). The event was considered serious for the following reasons: results in death, and other medically important serious event. The event occurred 107 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute coronary syndrome and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [7.66 mU/L, range = (0.55 - 4.78)], high bilirubin [24 umol/L, range = (3 - 21)], high creatine kinase [206 IU/L, range = (20 - 203)], and high creatinine [126 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high protein [2+, range = NEGATIVE, BL =normal], and high urate [470 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 345) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL ISCHAEMIA [ISCHAEMIC HEART DISEASE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 123) the subject experienced myocardial ischaemia [ischaemic heart disease] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 38 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial ischaemia and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high glucose [7.9 mmol/L, range = (4.1 - 5.9)], high glucose [1+, range = NEGATIVE], low hemoglobin [114 g/L, range = (116 - 162)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.35 mmol/L, range = (0.65 - 1.05)], high occult blood [1+, range = NEGATIVE], high protein [2+, range = NEGATIVE], and high urate [416 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14), BL =normal], high creatinine [87 umol/L, range = (44 - 80), BL =normal], and low hematocrit [0.34 fraction of 1, range = (0.35 - 0.47), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 123) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 900) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 58 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [113 umol/L, range = (62 - 106)], high glucose [8.7 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high hematocrit [0.55 fraction of 1, range = (0.37 - 0.5)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 842), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [205 IU/L, range = (20 - 203), BL =normal], normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high], high leukocytes [13.5 10^9/L, range = (4.1 - 12.3), BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 900) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 670) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 74 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.72 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], low albumin [31 g/L, range = (35 - 52)], high creatine kinase [286 IU/L, range = (24 - 250)], high creatinine [168 umol/L, range = (62 - 106)], high erythrocytes [6-8 /HPF, range = 0-5], high glucose [trace, range = NEGATIVE], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [128 g/L, range = (130 - 175)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [269 U/L, range = (5 - 250)], high occult blood [2+, range = NEGATIVE], high protein [3+, range = NEGATIVE], and low protein [59 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 498), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [167 U/L, range = (40 - 129), BL =normal], high blood urea nitrogen [8.93 mmol/L, range = (2.14 - 7.14), BL =normal], low calcium [2.03 mmol/L, range = (2.1 - 2.58), BL =normal], normal protein [4+, range = NEGATIVE, BL =high], and high urate [434 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 670) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 509) the subject experienced cardiac failure chronic [heart failure nyha class iii] (Grade 4) and on PPD (Day 513) the subject died. The event was considered serious for the following reasons: results in death. The event occurred 90 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [212 IU/L, range = (24 - 160)], high creatinine [88 umol/L, range = (44 - 80)], high glucose [11.2 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high potassium [5.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21), BL =normal], high glucose [1+, range = NEGATIVE, BL =normal], normal potassium [4.5 mmol/L, range = (3.3 - 5.1), BL =high], high protein [trace, range = NEGATIVE, BL =normal], and high urate [428 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 513) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NON CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 444) the subject experienced death [death non cardiovascular] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 106 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.54 mU/L, range = (0.55 - 4.78)], low creatinine [40 umol/L, range = (44 - 80)], high glucose [16 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [52 umol/L, range = (44 - 80), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 444) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ADENOCARCINOMA PANCREAS [ADENOCARCINOMA PANCREAS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 967) the subject experienced adenocarcinoma pancreas (Grade 4) and on PPD (Day 982) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 29 days after the last dose of any study medication.

Concomitant medications taken at the onset of the adenocarcinoma pancreas and up to 30 days prior to event onset included: atorvastatin, and cefuroxim.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.13 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], high creatinine [124 umol/L, range = (44 - 80)], low erythrocytes [3.7 10^12/L, range = (3.8 - 5.4)], low glucose [4.3 mmol/L, range = (4.6 - 6.4)], high lactate dehydrogenase [253 U/L, range = (5 - 250)], and high urate [529 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 840), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [38 U/L, range = (4 - 33), BL =normal], high alkaline phosphatase [154 U/L, range = (35 - 104), BL =normal], high aspartate aminotransferase [46 U/L, range = (4 - 31), BL =normal], normal blood urea nitrogen [5.82 mmol/L, range = (2.86 - 8.21), BL =high], high creatine kinase [264 IU/L, range = (24 - 160), BL =normal], normal creatinine [75 umol/L, range = (44 - 80), BL =high], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], normal glucose [5.6 mmol/L, range = (4.6 - 6.4), BL =low], low hematocrit [0.31 fraction of 1, range = (0.33 - 0.46), BL =normal], low hemoglobin [101 g/L, range = (110 - 161), BL =normal], normal lactate dehydrogenase [242 U/L, range = (5 - 250), BL =high], high sodium [148 mmol/L, range = (135 - 147), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 982) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 672) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 671 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.1 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [34 U/L, range = (40 - 129)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high calcium [2.58 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55)], high creatine kinase [302 IU/L, range = (20 - 203)], high creatinine [140 umol/L, range = (62 - 106)], high glucose [14.6 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [121 g/L, range = (130 - 177)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], and low urate [196 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.43 mmol/L, range = (2.86 - 8.21), BL =high], normal hematocrit [0.37 fraction of 1, range = (0.37 - 0.5), BL =low], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 672) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE RESPIRATORY FAILURE [ACUTE RESPIRATORY INSUFFICIENCY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 442) the subject experienced acute respiratory failure [acute respiratory insufficiency] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 65 days after the last dose of any study medication.

Concomitant medications taken at the onset of the acute respiratory failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.46 mg/L, range = (0 - 3)], high erythrocytes [9-14 /HPF, range = 0-5], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [2+, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 335), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 442) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD
PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 563) the subject experienced sudden death [sudden death, cause unknown] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.39 mg/L, range = (0 - 3)], high alanine aminotransferase [88 U/L, range = (4 - 41)], high aspartate aminotransferase [92 U/L, range = (4 - 37)], high creatine kinase [324 IU/L, range = (24 - 250)], low erythrocytes [3.5 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [125 g/L, range = (130 - 175)], high lactate dehydrogenase [313 U/L, range = (5 - 250)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high protein [1+, range = NEGATIVE], and high sodium [148 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [14 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [17 U/L, range = (4 - 37), BL =high], high bilirubin [1+, range = NEGATIVE, BL =normal], normal creatine kinase [67 IU/L, range = (24 - 250), BL =high], high

creatinine [110 umol/L, range = (62 - 106), BL =normal], normal erythrocytes [4.4 10^12/L, range = (4.1 - 5.9), BL =low], normal hematocrit [0.45 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [150 g/L, range = (130 - 175), BL =low], normal lactate dehydrogenase [195 U/L, range = (5 - 250), BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], normal magnesium [0.86 mmol/L, range = (0.65 - 1.05), BL =low], and normal sodium [141 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 563) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GASTRIC CANCER STAGE IV [GASTRIC CANCER STAGE IV WITH METASTASES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 72) the subject experienced gastric cancer stage iv [gastric cancer stage iv with metastases] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and requires or prolongs hospitalization. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastric cancer stage iv and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [12.98 mg/L, range = (0 - 3)], high glucose [9.1 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 72) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 92) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 7 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, clopidogrel, fenofibrate, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high creatinine [120 umol/L, range = (62 - 106)], low erythrocytes [4 10^12/L, range = (4.1 - 5.9)], high glucose [9.9 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [121 g/L, range = (130 - 175)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], high protein [2+, range = NEGATIVE], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14), BL =normal], low magnesium [0.55 mmol/L, range = (0.65 - 1.05), BL =normal], and low protein [59 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 92) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SQUAMOUS CELL CARCINOMA OF LUNG [SQUAMOUS CELL CARCINOMA OF LUNG]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 562) the subject experienced squamous cell carcinoma of lung (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the squamous cell carcinoma of lung and up to 30 days prior to event onset included: amoksiklav, atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [14.9 mg/L, range = (0 - 3)], low lymphocytes [12.5 %, range = (15.5 - 46.6)], high neutrophils [81.4 %, range = (40.9 - 77)], and high neutrophils [9.85 10^9/L, range = (2.03 - 8.36)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], high calcium [2.65 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.78 mmol/L, range = (2.1 - 2.58), BL =normal], low hemoglobin [122 g/L, range = (130 - 175), BL =normal], and high platelets [465 10^9/L, range = (140 - 450), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 562) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 246) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 18 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low creatinine [57 umol/L, range = (62 - 106)], low erythrocytes [3.8 10^12/L, range = (4.1 - 5.9)], high glucose [9.7 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [119 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], and low urate [178 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high protein [trace, range = NEGATIVE, BL =normal], and normal urate [220 umol/L, range = (202 - 416), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 246) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIOPULMONARY FAILURE [CARDIOPULMONARY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 281) the subject experienced cardiopulmonary failure (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiopulmonary failure and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, atorvastatin, clopidogrel, diflucan 150mg daily from PPD to PPD, and medoclav 625mg 3xdaily.

The subject had the following abnormal laboratory test results at baseline: high CRP [29.68 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high glucose [7.3 mmol/L, range = (4.6 - 6.4)], high protein [2+, range = NEGATIVE], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 168), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [137 U/L, range = (40 - 129), BL =normal], normal bilirubin [negative, range = NEGATIVE, BL =high], normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high], normal protein [negative, range = NEGATIVE, BL =high], normal urate [381 umol/L, range = (202 - 416), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 281) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPSIS [SEPSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 123) the subject experienced sepsis (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 2 days after the last dose of any study medication.

Concomitant medications taken at the onset of the sepsis and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [82 umol/L, range = (44 - 80)], high glucose [6.6 mmol/L, range = (4.6 - 6.4)], low leukocytes [3.7 10^9/L, range = (4.1 - 12.3)], and high sodium [148 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 83), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [62 umol/L, range = (44 - 80), BL =high], normal leukocytes [5.1 10^9/L, range = (4.1 - 12.3), BL =low], and normal sodium [141 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 123) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIOPULMONARY FAILURE [CARDIOPULMONARY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 665) the subject experienced cardiopulmonary failure (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 664 days after the first dose of any study medication.

Concomitant medications taken at the onset of the cardiopulmonary failure and up to 30 days prior to event onset included: 1.amoxicillin, 2.beta-lactamase inhibitors, atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [66 U/L, range = (4 - 41)], high aspartate aminotransferase [47 U/L, range = (4 - 37)], high glucose [11.5 mmol/L, range = (4.6 - 6.4)], high glucose [1+, range = NEGATIVE], and high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [15 U/L, range = (4 - 41), BL =high], normal aspartate aminotransferase [14 U/L, range = (4 - 37), BL =high], high bilirubin [1+, range = NEGATIVE, BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], low magnesium [0.55 mmol/L, range = (0.65 - 1.05), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 665) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 460) the subject experienced pneumonia [bronchopneumonia] (Grade 4) and PPD (Day 462) the subject died due to the event. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 37 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.86 mg/L, range = (0 - 3)], high calcium [2.65 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.65 mmol/L, range = (2.1 - 2.58)], high glucose [17 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.14 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [0.52 mg/L, range = (0 - 3), BL =high], normal calcium [2.38 mmol/L, range = (2.1 - 2.58), BL =high], and normal calcium corrected [2.38 mmol/L, range = (2.1 - 2.58), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 462) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 162) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 21 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.37 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high glucose [8.4 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and normal glucose [5.7 mmol/L, range = (4.1 - 5.9), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 162) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 807) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 4 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.45 mg/L, range = (0 - 3)], high glucose [9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [35 U/L, range = (4 - 33), BL =normal], low erythrocytes [3.4 10^12/L, range = (3.8 - 5.4), BL =normal], high glucose [1+, range = NEGATIVE, BL =normal], low hematocrit [0.32 fraction of 1, range = (0.33 - 0.46), BL =normal], low hemoglobin [102 g/L, range = (110 - 161), BL =normal], and high leukocytes [13-30 /HPF, range = 0-12, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 807) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): AORTIC DISSECTION RUPTURE [DESCENDING AORTIC DISSECTION RUPTURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 68) the subject experienced aortic dissection rupture [descending aortic dissection rupture] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the aortic dissection rupture and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.48 mg/L, range = (0 - 3)], high thyrotropin [5.49 mU/L, range = (0.55 - 4.78)], high creatine kinase [274 IU/L, range = (20 - 203)], high glucose [9.1 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 68) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 109) the subject experienced pneumonia [bronchopneumonia] (Grade 4) and on PPD (Day 132) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 37 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [16.4 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], and high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 132) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [ASYSTOLIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Non-Cardiovascular Procedure Or Surgery)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 534) the subject experienced cardiac arrest [asystolia] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, and results in death. The event occurred 14 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [223 IU/L, range = (20 - 203)], and low erythrocytes [3.9 10^12/L, range = (4 - 5.8)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [132 U/L, range = (40 - 129), BL =normal], normal creatine kinase [170 IU/L, range = (20 - 203), BL =high], normal erythrocytes [4.7 10^12/L, range = (4 - 5.8), BL =low], high urate [476 umol/L, range = (202 - 416), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 534) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Pulmonary Emboli)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 134) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 50 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 84), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [7.4 mmol/L, range = (4.6 - 6.4), BL =normal], and high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 134) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOGENIC SHOCK [CARDIOGENIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 667) the subject experienced cardiogenic shock (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 9 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiogenic shock and up to 30 days prior to event onset included: amoksiklav 1000 mg, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.33 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high glucose [9.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [523 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.43 mmol/L, range = (2.86 - 8.21), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 667) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ATRIAL FIBRILLATION [ATRIAL FIBRILLATION AGGRAVATED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 559) the subject experienced atrial fibrillation [atrial fibrillation aggravated] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 68 days after the last dose of any study medication.

Concomitant medications taken at the onset of the atrial fibrillation and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [139 U/L, range = (40 - 129)], high aspartate aminotransferase [42 U/L, range = (4 - 37)], high blood urea nitrogen [12.14 mmol/L, range = (2.86 - 8.21)], high creatinine [111 umol/L, range = (62 - 106)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [30 g/L, range = (35 - 52), BL =normal], normal aspartate aminotransferase [30 U/L, range = (4 - 37), BL =high], high CRP [21.62 mg/L, range = (0 - 3), BL =normal], high potassium [5.6 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [589 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 559) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 592) the subject experienced sudden death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], and high thyrotropin [4.85 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [109 umol/L, range = (62 - 106), BL =normal], and low leukocytes [3.8 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 592) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ANGINA UNSTABLE [ANGINA UNSTABLE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 435) the subject experienced angina unstable. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the angina unstable and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high glucose [7.7 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [1+, range = NEGATIVE, BL =normal], and low sodium [131 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 435) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 803) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 361 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.39 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [14.28 mmol/L, range = (2.86 - 8.21)], high creatinine [215 umol/L, range = (62 - 106)], low hemoglobin [128 g/L, range = (130 - 177)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], and high urate [565 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 308), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [1.49 mg/L, range = (0 - 3), BL =high], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], high lactate dehydrogenase [275 U/L, range = (5 - 250), BL =normal], high leukocytes [13 10^9/L, range = (4.1 - 12.3), BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 803) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY OEDEMA [PULMONARY OEDEMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 469) the subject experienced cardiac failure [heart failure event - urgent visit] (Grade 4) and pulmonary oedema (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary oedema and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.48 mg/L, range = (0 - 3)], high blood urea nitrogen [12.5 mmol/L, range = (2.86 - 8.21)], high creatinine [135 umol/L, range = (62 - 106)], high glucose [11.9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.13 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.4 mmol/L, range = (0.65 - 1.05)], and high urate [636 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 340), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.07 mmol/L, range = (2.86 - 8.21), BL =high], normal CRP [1.25 mg/L, range = (0 - 3), BL =high], normal creatinine [97 umol/L, range = (62 - 106), BL =high], low erythrocytes [3.8 10^12/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.35 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [113 g/L, range = (130 - 175), BL =normal], and high leukocytes [12.6 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 469) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 393) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 393) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 662) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 633 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.1 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 662) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 625) the subject experienced death. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 372 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [22.65 mg/L, range = (0 - 3)], high occult blood [1+, range = NEGATIVE], high protein [1+, range = NEGATIVE], high alkaline phosphatase [115 U/L, range = (35 - 104)], high creatinine [81 umol/L, range = (44 - 80)], high glucose [6.8 mmol/L, range = (4.1 - 5.9)], high hematocrit [0.5 fraction of 1, range = (0.35 - 0.47)], high hemoglobin [164 g/L, range = (116 - 162)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [393 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 330), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [90 U/L, range = (35 - 104), BL =high], normal creatinine [72 umol/L, range = (44 - 80), BL =high], normal hemoglobin [162 g/L, range = (116 - 162), BL =high], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 625) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 326) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 73 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [25.27 mg/L, range = (0 - 3)], high alkaline phosphatase [131 U/L, range = (40 - 129)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 175), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [128 U/L, range = (40 - 129), BL =high], low calcium [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], and low creatinine [61 umol/L, range = (62 - 106), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 326) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 443) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, beta blocker, and doxycyl.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.92 mg/L, range = (0 - 3)], low thyrotropin [0.45 mU/L, range = (0.55 - 4.78)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high leukocytes [13.6 10^9/L, range = (4.1 - 12.3)], low potassium [3.2 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], and high urate [535 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 339), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [123 U/L, range = (35 - 104), BL =normal], high calcium [2.65 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55), BL =normal], high glucose [7.2 mmol/L, range = (4.6 - 6.4), BL =normal], high hematocrit [0.48 fraction of 1, range = (0.33 - 0.46), BL =normal], high lactate dehydrogenase [375 U/L, range = (5 - 250), BL =normal], and normal potassium [3.5 mmol/L, range = (3.3 - 5.1), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 443) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [CEREBROVASCULAR ACCIDENT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 333) the subject experienced cerebrovascular accident (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 248 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.41 mg/L, range = (0 - 3)], high alanine aminotransferase [37 U/L, range = (4 - 33)], high alkaline phosphatase [183 U/L, range = (35 - 104)], high glucose [17.7 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], and high HbA1c [0.16 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 176), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [35 U/L, range = (4 - 31), BL =normal], high occult blood [trace, range = NEGATIVE, BL =normal], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 333) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [DEATH CARDIOVASCULAR]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 281) the subject experienced cardiovascular disorder [death cardiovascular] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, and fluconazole.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.37 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [137 U/L, range = (35 - 104)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high creatine kinase [175 IU/L, range = (24 - 170)], high creatinine [130 umol/L, range = (44 - 80)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [277 U/L, range = (5 - 250)], high protein [91 g/L, range = (60 - 80)], and high urate [559 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [34 U/L, range = (4 - 33), BL =normal], high calcium [2.65 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.65 mmol/L, range = (2.1 - 2.58), BL =normal], high hematocrit [0.47 fraction of 1, range = (0.35 - 0.47), BL =normal], and normal lactate dehydrogenase [214 U/L, range = (5 - 250), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 281) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 197) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.01 mg/L, range = (0 - 3)], high erythrocytes [5.9 10^12/L, range = (3.8 - 5.4)], low glucose [4.3 mmol/L, range = (4.6 - 6.4)], and high hematocrit [0.49 fraction of 1, range = (0.33 - 0.46)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high hemoglobin [164 g/L, range = (110 - 161), BL =normal], and normal leukocytes [0-3 /HPF, range = 0-12, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 197) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 843) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, atorvastatin, bactrim, beta blocker, levofloxacin, levofloxacin 1000 mg, purbac, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high creatinine [119 umol/L, range = (62 - 106)], and high erythrocytes [6 10^12/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 842), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [88 umol/L, range = (62 - 106), BL =high], normal erythrocytes [4.9 10^12/L, range = (4 - 5.8), BL =high], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high leukocytes [13-30 /HPF, range = 0-3, BL = missing], and high occult blood [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 843) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LARGE INTESTINE PERFORATION [PERFORATED COLON]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Gastrointestinal)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 151) the subject experienced large intestine perforation [perforated colon] (Grade 3). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and requires or prolongs hospitalization. The event occurred 66 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the large intestine perforation and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [17.85 mg/L, range = (0 - 3)], high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], and low hemoglobin [117 g/L, range = (130 - 175)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [16.2 10^9/L, range = (4.1 - 12.3), BL =normal], and low protein [57 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 151) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 693) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, amoxicillin, analgesic or antipyretic agent, atorvastatin, augmentin, beta blocker, fenofibrate, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [28 U/L, range = (40 - 129)], high creatinine [113 umol/L, range = (62 - 106)], and low leukocytes [3.6 10^9/L, range = (4.1 - 12.3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.1 mmol/L, range = (2.86 - 8.21), BL =normal], and high creatine kinase [287 IU/L, range = (20 - 203), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 693) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): COMPLETED SUICIDE [SUICIDE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Suicide)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 308) the subject experienced completed suicide [suicide] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 59 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the completed suicide and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high urate [494 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 173), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [51 U/L, range = (4 - 41), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 308) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ORGAN FAILURE [ORGAN FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 254) the subject experienced organ failure. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 99 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the organ failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.02 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [134 U/L, range = (40 - 129)], high creatinine [118 umol/L, range = (62 - 106)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 254) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 71) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 3 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.88 mg/L, range = (0 - 3)], high thyrotropin [6.45 mU/L, range = (0.55 - 4.78)], high direct bilirubin [7 umol/L, range = (0 - 5)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], high glucose [13.2 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [115 g/L, range = (130 - 177)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [547 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 71) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [FOUND DEAD (CAUSE UNDETERMINED)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 395) the subject experienced death [found dead (cause undetermined)]. The event was considered serious for the following reasons: results in death. The event occurred 58 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin, and tavanic.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high aspartate aminotransferase [36 U/L, range = (4 - 31)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatine kinase [224 IU/L, range = (24 - 160)], high creatinine [89 umol/L, range = (44 - 80)], low glucose [3.8 mmol/L, range = (4.6 - 6.4)], and high occult blood [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 254), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [23 U/L, range = (4 - 31), BL =high], normal glucose [4.6 mmol/L, range = (4.6 - 6.4), BL =low], high leukocytes [tntc /HPF, range = 0-12, BL = missing], and high urate [464 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 395) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 643) the subject experienced death [unknown cause of death]. The event was considered serious for the following reasons: results in death. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.37 mg/L, range = (0 - 3)], high alanine aminotransferase [55 U/L, range = (4 - 41)], high protein [trace, range = NEGATIVE], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [39 U/L, range = (4 - 41), BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 643) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 220) the subject experienced pneumonia (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 205 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: avelon, and invanz.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.8 mg/L, range = (0 - 3)], and low creatinine [61 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 220) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SHOCK [HAEMODYNAMIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 215) the subject experienced shock [haemodynamic shock] (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 18 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the shock and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [43.82 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.57 mmol/L, range = (2.14 - 7.14)], high creatinine [118 umol/L, range = (62 - 106)], high glucose [7.3 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [116 g/L, range = (130 - 175)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high protein [1+, range = NEGATIVE], high protein [84 g/L, range = (60 - 80)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 91), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [255 IU/L, range = (24 - 250), BL =normal], low erythrocytes [4 10^12/L, range = (4.1 - 5.9), BL =normal], high lactate dehydrogenase [263 U/L, range = (5 - 250), BL =normal], and normal protein [78 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 215) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 71) the subject was reported with myocardial infarction (Grade 4) and PPD (Day 71) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 70 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.19 mg/L, range = (0 - 3)], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 71) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ULCER HAEMORRHAGE [BLEEDING ULCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 248) the subject experienced ulcer haemorrhage [bleeding ulcer] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the ulcer haemorrhage and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [30 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], high calcium [2.63 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55)], high creatinine [141 umol/L, range = (62 - 106)], high glucose [8.1 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [305 U/L, range = (5 - 250)], high potassium [6.2 mmol/L, range = (3.3 - 5.1)], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [43 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [40 U/L, range = (4 - 37), BL =normal], normal calcium [2.45 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.45 mmol/L, range = (2.2 - 2.55), BL =high], normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], high occult blood [trace, range = NEGATIVE, BL =normal], low platelets [118 10^9/L, range = (140 - 450), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to statin. The event ended on PPD (Day 248) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 395) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 240 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.17 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14)], high creatinine [129 umol/L, range = (62 - 106)], high glucose [7.9 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], and high urate [630 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 100), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.75 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.75 mmol/L, range = (2.1 - 2.58), BL =normal], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [123 g/L, range = (130 - 175), BL =normal], low magnesium [0.55 mmol/L, range = (0.65 - 1.05), BL =normal], high potassium [6 mmol/L, range = (3.3 - 5.1), BL =normal], high sodium [148 mmol/L, range = (135 - 147), BL =normal], and normal urate [345 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 395) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 127) the subject experienced pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 126 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.49 mg/L, range = (0 - 3)], high erythrocytes [31-50 /HPF, range = 0-5], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [trace, range = NEGATIVE], high protein [1+, range = NEGATIVE], and low protein [59 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [32 g/L, range = (35 - 52), BL =normal], and low calcium [2.08 mmol/L, range = (2.2 - 2.55), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 127) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 609) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, ezetimibe, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and normal urate [387 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 609) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 435) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 434 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14)], high creatinine [118 umol/L, range = (62 - 106)], low erythrocytes [4 10^12/L, range = (4.1 - 5.9)], low glucose [3.6 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [125 g/L, range = (130 - 175)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [506 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 435) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GENERALISED TONIC-CLONIC SEIZURE [GRAND MAL SEIZURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 99) the subject experienced generalised tonic-clonic seizure [grand mal seizure] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the generalised tonic-clonic seizure and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10 mmol/L, range = (2.14 - 7.14)], high CRP [3.16 mg/L, range = (0 - 3)], high creatinine [120 umol/L, range = (62 - 106)], high glucose [8.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], and high protein [86 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [5 mmol/L, range = (2.14 - 7.14), BL =high], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [121 g/L, range = (130 - 175), BL =normal], and normal protein [74 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 99) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 6) the subject experienced acute myocardial infarction [acute mycardial infarction] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, angiotensin receptor blocker, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: low calcium [2.15 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2.18 mmol/L, range = (2.2 - 2.55)], and low platelets [101 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 6) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 336) the subject experienced death [death nos]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 335 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.28 mg/L, range = (0 - 3)], high erythrocytes [9-14 /HPF, range = 0-8], high glucose [16 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], low hemoglobin [108 g/L, range = (110 - 161)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.55 mmol/L, range = (0.65 - 1.05)], high occult blood [trace, range = NEGATIVE], high protein [1+, range = NEGATIVE], low sodium [133 mmol/L, range = (135 - 147)], and high urate [351 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 336) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 630) the subject experienced death [death nos] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 55 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low creatinine [48 umol/L, range = (62 - 106)], high glucose [13.1 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], and low urate [178 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 507), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [124 g/L, range = (130 - 175), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and normal urate [268 umol/L, range = (202 - 416), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 630) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 456) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [264 U/L, range = (40 - 129)], high glucose [7.2 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high protein [82 g/L, range = (60 - 80)], and high urate [517 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 345), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [94 U/L, range = (40 - 129), BL =high], high CRP [3.93 mg/L, range = (0 - 3), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], normal glucose [4.7 mmol/L, range = (4.6 - 6.4), BL =high], high occult blood [1+, range = NEGATIVE, BL =normal], normal protein [74 g/L, range = (60 - 80), BL =high], and normal urate [404 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 456) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 213) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.16 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [44 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high direct bilirubin [22 umol/L, range = (0 - 5)], high glucose [11.7 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.4 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [127 g/L, range = (130 - 175)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], and high urate [571 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 132), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [30 g/L, range = (35 - 52), BL =normal], high alkaline phosphatase [172 U/L, range = (40 - 129), BL =normal], normal bilirubin [21 umol/L, range = (3 - 21), BL =high], normal bilirubin [negative, range = NEGATIVE, BL =high], normal hematocrit [0.4 fraction of 1, range = (0.4 - 0.52), BL =low], high potassium [5.4 mmol/L, range = (3.3 - 5.1), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 213) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 567) the subject experienced death [death nos] (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 232 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and quinolone.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.26 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [136 umol/L, range = (62 - 106)], high glucose [3+, range = NEGATIVE], high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 349), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [8.4 mmol/L, range = (4.6 - 6.4), BL =normal], normal glucose [negative, range = NEGATIVE, BL =high], normal hematocrit [0.49 fraction of 1, range = (0.37 - 0.5), BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 567) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 584) the subject experienced death [death nos]. The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 262 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amoxycillin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [5.81 mU/L, range = (0.55 - 4.78)], high alanine aminotransferase [43 U/L, range = (4 - 41)], high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], high creatinine [111 umol/L, range = (62 - 106)], high glucose [7.2 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], low hemoglobin [125 g/L, range = (130 - 175)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], high protein [81 g/L, range = (60 - 80)], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [34 U/L, range = (4 - 41), BL =high], high aspartate aminotransferase [43 U/L, range = (4 - 37), BL =normal], normal creatinine [106 umol/L, range = (62 - 106), BL =high], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52), BL =normal], normal protein [79 g/L, range = (60 - 80), BL =high], and normal specific gravity [1.03, range = (1 - 1.04), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 584) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 452) the subject experienced sudden death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 128 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14)], high creatinine [111 umol/L, range = (62 - 106)], high glucose [6 mmol/L, range = (4.1 - 5.9)], low hemoglobin [128 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 395), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [169 U/L, range = (40 - 129), BL =normal], high bilirubin [29 umol/L, range = (3 - 21), BL =normal], high CRP [3.64 mg/L, range = (0 - 3), BL =normal], high direct bilirubin [15 umol/L, range = (0 - 5), BL =normal], normal glucose [5.7 mmol/L, range = (4.1 - 5.9), BL =high], low hematocrit [0.4 fraction of 1, range = (0.4 - 0.52), BL =normal], high lactate dehydrogenase [267 U/L, range = (5 - 250), BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 452) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 415) the subject experienced sudden death [sudden death, cause unknown]. The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 70 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [5.7 mU/L, range = (0.55 - 4.78)], high creatinine [117 umol/L, range = (62 - 106)], low erythrocytes [3.5 10^12/L, range = (4 - 5.8)], high glucose [7.1 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.29 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [91 g/L, range = (130 - 177)], high protein [trace, range = NEGATIVE], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 369), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [22.61 mg/L, range = (0 - 3), BL =normal], normal creatinine [90 umol/L, range = (62 - 106), BL =high], normal erythrocytes [4.1 10^12/L, range = (4 - 5.8), BL =low], normal glucose [4.8 mmol/L, range = (4.6 - 6.4), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 415) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD .

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 80) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.59 mg/L, range = (0 - 3)], high glucose [6.9 mmol/L, range = (4.1 - 5.9)], high hematocrit [0.53 fraction of 1, range = (0.4 - 0.52)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [535 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 80) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CIRCULATORY COLLAPSE [SUDDEN CARDIOVASCULAR COLLAPSE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 249) the subject experienced circulatory collapse [sudden cardiovascular collapse] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 136 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the circulatory collapse and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [216 IU/L, range = (20 - 203)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 92), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [29 umol/L, range = (3 - 21), BL =normal], low calcium [2.13 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.15 mmol/L, range = (2.2 - 2.55), BL =normal], normal creatine kinase [46 IU/L, range = (20 - 203), BL =high], high direct bilirubin [9 umol/L, range = (0 - 5), BL =normal], and high leukocytes [14.8 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 249) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 327) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.82 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], low albumin [33 g/L, range = (35 - 52)], high alkaline phosphatase [174 U/L, range = (35 - 104)], low bilirubin [2 umol/L, range = (3 - 21)], high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high creatinine [103 umol/L, range = (44 - 80)], high erythrocytes [5.8 10^12/L, range = (3.8 - 5.4)], high glucose [7.7 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high hematocrit [0.5 fraction of 1, range = (0.33 - 0.46)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high potassium [6 mmol/L, range = (3.3 - 5.1)], high protein [3+, range = NEGATIVE], and high urate [404 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 173), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [3 umol/L, range = (3 - 21), BL =low], normal blood urea nitrogen [7.85 mmol/L, range = (2.86 - 8.21), BL =high], low calcium [2.1 mmol/L, range = (2.2 - 2.55), BL =normal], normal potassium [4.4 mmol/L, range = (3.3 - 5.1), BL =high], and low protein [58 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 327) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 146) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 60 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.75 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high creatinine [106 umol/L, range = (44 - 80)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [13.4 10^9/L, range = (4.1 - 12.3)], high occult blood [trace, range = NEGATIVE], high protein [1+, range = NEGATIVE], and high urate [422 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [309 IU/L, range = (24 - 160), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 146) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE CONGESTIVE [CONGESTIVE CARDIAC FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 224) the subject experienced cardiac failure congestive [congestive cardiac failure]. The event was considered serious for the following reasons: results in death. The event occurred 55 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure congestive and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.5 mg/L, range = (0 - 3)], low erythrocytes [3.7 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [123 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [trace, range = NEGATIVE], and high urate [541 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.68 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.68 mmol/L, range = (2.1 - 2.58), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], high glucose [7 mmol/L, range = (4.1 - 5.9), BL =normal], normal hematocrit [0.42 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [134 g/L, range = (130 - 175), BL =low], normal HbA1c [0.05 fraction of 1, range = (0.04 - 0.06), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 224) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLUS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 582) the subject experienced pulmonary embolism [pulmonary embolus] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.11 mg/L, range = (0 - 3)], high aspartate aminotransferase [41 U/L, range = (4 - 37)], high calcium [2.65 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.65 mmol/L, range = (2.1 - 2.58)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [266 U/L, range = (5 - 250)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], and high urate [726 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], and normal magnesium [0.66 mmol/L, range = (0.65 - 1.05), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 582) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 381) the subject experienced death (Grade 3). The event was considered serious for the following reasons: results in death. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: aspen cefpodoxine, over the counter omega-3 fish oil, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21), BL =normal], low platelets [124 10^9/L, range = (140 - 450), BL =normal], and high urate [422 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 381) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): METASTASIS [METASTASIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 88) the subject experienced metastasis (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 42 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the metastasis and up to 30 days prior to event onset included: atorvastatin, and flaxseed oil.

The subject had the following abnormal laboratory test results at baseline: high CRP [40.16 mg/L, range = (0 - 3)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high lactate dehydrogenase [307 U/L, range = (5 - 250)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 88) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GASTROENTERITIS [CHRONIC GASTROENTERITIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 283) the subject experienced gastroenteritis [chronic gastroenteritis] (Grade 3). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 30 days after the last dose of any study medication.

Concomitant medications taken at the onset of the gastroenteritis and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low lymphocytes [0.87 10^9/L, range = (1.02 - 3.36)], low monocytes [0.15 10^9/L, range = (0.18 - 0.9)], high erythrocytes [31-50 /HPF, range = 0-5], high glucose [8.6 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.4 fraction of 1, range = (0.4 - 0.52)], high leukocytes [tntc /HPF, range = 0-3], high occult blood [3+, range = NEGATIVE], low platelets [59 10^9/L, range = (140 - 450)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [93 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 283) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MESOTHELIOMA [PROGRESSION OF MESOTHELIOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 649) the subject experienced mesothelioma [progression of mesothelioma] (Grade 3). The event was considered serious for the following reasons: results in death. The event occurred 158 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the mesothelioma and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [40 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], and high creatinine [141 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.07 mmol/L, range = (2.86 - 8.21), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 649) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): BRAIN CANCER METASTATIC [BRAIN CANCER METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 57) the subject experienced brain cancer metastatic (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the brain cancer metastatic and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.25 mg/L, range = (0 - 3)], high calcium [2.7 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.7 mmol/L, range = (2.2 - 2.55)], high erythrocytes [5.9 10^12/L, range = (3.8 - 5.4)], high hematocrit [0.49 fraction of 1, range = (0.33 - 0.46)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [321 U/L, range = (5 - 250)], and high urate [345 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 57) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 157) the subject experienced pneumonia (Grade 3) and on PPD (Day 172) the subject experienced cardiogenic shock (Grade 4). On PPD (Day 207) the subject died due to pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 60 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.14 mmol/L, range = (2.86 - 8.21)], high creatinine [213 umol/L, range = (62 - 106)], low glucose [<2.2 mmol/L], low hematocrit [0.36 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [115 g/L, range = (130 - 175)], high magnesium [1.1 mmol/L, range = (0.65 - 1.05)], high potassium [5.6 mmol/L, range = (3.3 - 5.1)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 89), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], normal magnesium [1.05 mmol/L, range = (0.65 - 1.05), BL =high], and normal urate [387 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 207) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH UNDERMINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 660) the subject experienced death [death undermined] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 78 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high protein [2+, range = NEGATIVE], low calcium [2.18 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2.18 mmol/L, range = (2.2 - 2.55)], and high hematocrit [0.53 fraction of 1, range = (0.37 - 0.5)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 512), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.68 mmol/L, range = (2.86 - 8.21), BL =normal], normal calcium [2.41 mmol/L, range = (2.2 - 2.55), BL =low], normal calcium corrected [2.4 mmol/L, range = (2.2 - 2.55), BL =low], normal hematocrit [0.45 fraction of 1, range = (0.37 - 0.5), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and low sodium [131 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 660) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PAIN IN EXTREMITY [BILATERAL LEG PAIN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 313) the subject experienced pain in extremity [bilateral leg pain] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 312 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pain in extremity and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.78 mg/L, range = (0 - 3)], low hematocrit [0.4 fraction of 1, range = (0.4 - 0.52)], high protein [trace, range = NEGATIVE], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], normal hematocrit [0.43 fraction of 1, range = (0.4 - 0.52), BL =low], low leukocytes [3.7 10^9/L, range = (4.1 - 12.3), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 313) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 534) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 463 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.42 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 128), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [10.71 mmol/L, range = (2.14 - 7.14), BL =normal], normal CRP [1.72 mg/L, range = (0 - 3), BL =high], high creatinine [109 umol/L, range = (62 - 106), BL =normal], high glucose [6.7 mmol/L, range = (4.1 - 5.9), BL =normal], and high urate [577 umol/L, range = (202 - 416), BL =normal].

Action taken with IP and statin was not reported.The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 534) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 356) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 355 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [22 umol/L, range = (3 - 21)], high creatinine [107 umol/L, range = (62 - 106)], high glucose [7.2 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 356) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): URINARY TRACT INFECTION [URINARY TRACT INFECTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 524) the subject experienced urinary tract infection (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and other medically important serious event. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the urinary tract infection and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, ciprofloxacin hcl, clopidogrel, glycemic control medication, and tazoperan inj 2.25g.

The subject had the following abnormal laboratory test results at baseline: low erythrocytes [3.6 10^12/L, range = (3.8 - 5.4)], high glucose [6.5 mmol/L, range = (4.6 - 6.4)], high protein [1+, range = NEGATIVE], and high urate [404 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], high erythrocytes [9-14 /HPF, range = 0-8, BL = missing], low hematocrit [0.29 fraction of 1, range = (0.33 - 0.46), BL =normal], low hemoglobin [92 g/L, range = (110 - 161), BL =normal], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06), BL = missing], high leukocytes [tntc /HPF, range = 0-12, BL = missing], and high occult blood [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 524) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [NATURAL DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 233) the subject experienced death [natural death] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 60 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high glucose [14.5 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], and high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 173), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], and high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 233) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 389) the subject experienced death [unknown death] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 143 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [114 U/L, range = (35 - 104)], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [99 U/L, range = (35 - 104), BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], and high urate [363 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 389) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [FOUND DEAD (CAUSE UNDETERMINED)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1095) the subject experienced death [found dead (cause undetermined)] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 758 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.3 mg/L, range = (0 - 3)], and high glucose [6.3 mmol/L, range = (4.1 - 5.9)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [280 IU/L, range = (24 - 250), BL =normal], normal glucose [5.8 mmol/L, range = (4.1 - 5.9), BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1095) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [HEART ATTACK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 560) the subject experienced myocardial infarction [heart attack] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 6 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 502), the subject had the following on-study laboratory test results with results different than baseline: high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 560) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 543) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline: high bilirubin [22 umol/L, range = (3 - 21), BL =normal], and high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 543) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 367) the subject experienced death [death nos] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 198 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: myoxam 600.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.66 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [106 U/L, range = (35 - 104)], high creatinine [92 umol/L, range = (44 - 80)], high leukocytes [13.1 10^9/L, range = (4.1 - 12.3)], and high urate [446 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [92 U/L, range = (35 - 104), BL =high], and normal leukocytes [12.1 10^9/L, range = (4.1 - 12.3), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 367) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Pulmonary Embolism)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 887) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 465 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, cifotaxim, cirofloxacin, and piperacillin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high leukocytes [4-12 /HPF, range = 0-3], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 853), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [50 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [49 U/L, range = (4 - 37), BL =normal], normal bilirubin [negative, range = NEGATIVE, BL =high], high glucose [7.6 mmol/L, range = (4.6 - 6.4), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 887) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 2) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, analgesic or antipyretic agent, angiotensin receptor blocker, antidepressants, beta blocker, fenofibrate, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [43 U/L, range = (4 - 41)], high aspartate aminotransferase [46 U/L, range = (4 - 37)], high bilirubin [1+, range = NEGATIVE], high creatinine [110 umol/L, range = (62 - 106)], high glucose [7.5 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high protein [2+, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 2) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE CHRONIC [HEART FAILURE NYHA CLASS IV]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 448) the subject experienced cardiac failure chronic [heart failure nyha class iv] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 371 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiac failure chronic and up to 30 days prior to event onset included: ACE inhibitor, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, glycemic control medication, insulin, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high prothrombin intl. normalized ratio [2.83, range = (0.5 - 1.5)], high prothrombin time [31.4 sec, range = (9.4 - 12.5)], high alanine aminotransferase [94 U/L, range = (4 - 41)], high alkaline phosphatase [255 U/L, range = (40 - 129)], high aspartate aminotransferase [68 U/L, range = (4 - 37)], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high CRP [3.4 mg/L, range = (0 - 3)], high glucose [8.4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and low platelets [124 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be related to IP and not related to statin. The event

ended on PPD (Day 448) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [MYOCARDIAL DECOMPENSATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 37) the subject experienced cardiac failure [myocardial decompensation] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.5 mmol/L, range = (2.86 - 8.21)], high creatinine [106 umol/L, range = (44 - 80)], high glucose [9.6 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high urate [506 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 37) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [MYOCARDIAL DECOMPENSATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 353) the subject experienced cardiac failure [myocardial decompensation] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 184 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: atorvastatin, ciprofloxacin, idotrim, and selexid.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high erythrocytes [tntc /HPF, range = 0-5], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-3], high occult blood [3+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.78 mmol/L, range = (2.86 - 8.21), BL =high], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], low platelets [123 10^9/L, range = (140 - 450), BL =normal], and low protein [59 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 353) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG ADENOCARCINOMA [LUNG ADENOCARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1022) the subject experienced lung adenocarcinoma. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 234 days after the last dose of any study medication.

Concomitant medications taken at the onset of the lung adenocarcinoma and up to 30 days prior to event onset included: amoxillin, atorvastatin, avelox, fludoxacillin, furadantin, klacid, peniccilin, and selexid.

The subject had the following abnormal laboratory test results at baseline: high CRP [24.9 mg/L, range = (0 - 3)], and high urate [345 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.5 mmol/L, range = (4.6 - 6.4), BL =normal], and normal urate [303 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1022) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 353) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 228 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [22 umol/L, range = (3 - 21)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 83), the subject had the following on-study laboratory test results with results different than baseline:** high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and normal thyrotropin [1.9 mU/L, range = (0.55 - 4.78), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 353) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 788) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 677), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [7.21 mmol/L, range = (2.14 - 7.14), BL =normal], and high glucose [6.3 mmol/L, range = (4.1 - 5.9), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 788) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [OUT OF HOSPITAL CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 906) the subject experienced cardiac failure [heart failure] (Grade 4) and cardiac arrest [out of hospital cardiac arrest] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 72 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.86 mg/L, range = (0 - 3)], high creatinine [126 umol/L, range = (62 - 106)], low erythrocytes [3.6 10^12/L, range = (4 - 5.8)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], low hemoglobin [123 g/L, range = (130 - 177)], low leukocytes [3.2 10^9/L, range = (4.1 - 12.3)], low platelets [126 10^9/L, range = (140 - 450)], high protein [1+, range = NEGATIVE], and high urate [506 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 834), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21), BL =normal], normal erythrocytes [4.1 10^12/L, range = (4 - 5.8), BL =low], normal hemoglobin [133 g/L, range = (130 - 177), BL =low], normal leukocytes [4.6 10^9/L, range = (4.1 - 12.3), BL =low], normal platelets [152 10^9/L, range = (140 - 450), BL =low], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 906) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE MYOCARDIAL INFARCTION [ACUTE MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 616) the subject experienced acute myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 27 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute myocardial infarction and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [72 U/L, range = (4 - 41)], high alkaline phosphatase [194 U/L, range = (40 - 129)], high aspartate aminotransferase [74 U/L, range = (4 - 37)], high creatinine [130 umol/L, range = (62 - 106)], high lactate dehydrogenase [265 U/L, range = (5 - 250)], low platelets [139 10^9/L, range = (140 - 450)], and high protein [82 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [22 U/L, range = (4 - 41), BL =high], normal alkaline phosphatase [125 U/L, range = (40 - 129), BL =high], normal aspartate aminotransferase [22 U/L, range = (4 - 37), BL =high], low erythrocytes [3.8 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [114 g/L, range = (130 - 177), BL =normal], normal lactate dehydrogenase [245 U/L, range = (5 - 250), BL =high], and normal protein [76 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 616) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 421) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 97 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high thyrotropin [6.57 mU/L, range = (0.55 - 4.78)], high alanine aminotransferase [54 U/L, range = (4 - 41)], high bilirubin [1+, range = NEGATIVE], high glucose [9.3 mmol/L, range = (4.1 - 5.9)], high glucose [trace, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], high protein [2+, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 365), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high CRP [7.12 mg/L, range = (0 - 3), BL =normal], normal specific gravity [1.03, range = (1 - 1.04), BL =high], and high urate [452 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 421) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE RESPIRATORY FAILURE [ACUTE RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1).). On PPD (Day 62) the subject experienced metastases to lung [lung metastases] (Grade 4) and on PPD (Day 70) the subject experienced acute respiratory failure. The event was considered serious for the following reasons: results in death. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute respiratory failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [21.09 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high hepatitis C virus antibody [positive, range = NEGATIVE], high hepatitis C virus antibody [positive, range = NEGATIVE], high alanine aminotransferase [49 U/L, range = (4 - 41)], high aspartate aminotransferase [51 U/L, range = (4 - 37)], high creatinine [111 umol/L, range = (62 - 106)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [268 U/L, range = (5 - 250)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 70) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [SUSPECTED MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 212) the subject experienced myocardial infarction [suspected myocardial infarction] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low creatinine [61 umol/L, range = (62 - 106)], and low glucose [4.4 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [6.2 mmol/L, range = (4.6 - 6.4), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 212) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): HAEMORRHAGE INTRACRANIAL [INTRACRANIAL HEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 785) the subject experienced haemorrhage intracranial [intracranial hemorrhage] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the haemorrhage intracranial and up to 30 days prior to event onset included: atorvastatin, and macrol 500 mg (clarithromycin).

The subject had the following abnormal laboratory test results at baseline: high CRP [4.53 mg/L, range = (0 - 3)], high creatinine [135 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [46 mL/min/1.73m2, range = (60 - 9999)], high glucose [8 mmol/L, range = (4.6 - 6.4)], and high urate [571 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 675), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.5 mmol/L, range = (4.6 - 6.4), BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], high occult blood [trace, range = NEGATIVE, BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 785) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 211) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [10.8 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 211) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 217) the subject experienced cerebral haemorrhage [cerebral hemorrhage] (Grade 4) and on PPD (Day 350) the subject died due to cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 139 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7 mmol/L, range = (4.1 - 5.9)], high occult blood [1+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 87), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [328 IU/L, range = (24 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 350) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 509) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 270 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.2 mg/L, range = (0 - 3)], low thyrotropin [0.31 mU/L, range = (0.55 - 4.78)], high glucose [12.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high potassium [5.4 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [6 mmol/L, range = (4.6 - 6.4), BL =high], normal potassium [4.3 mmol/L, range = (3.3 - 5.1), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 509) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 43) the subject experienced respiratory disorder (Grade 3) and on PPD (Day 46) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, beta blocker, fenofibrate, glycemic control medication, insulin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [32 U/L, range = (40 - 129)], high creatinine [130 umol/L, range = (62 - 106)], high glucose [6.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high potassium [5.7 mmol/L, range = (3.3 - 5.1)], and low urate [155 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 46) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): TRANSFUSION REACTION [MISMATCHED BLOOD TRANSFISION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Other Non-Cardiovascular) (Transfusion Reaction)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 68) the subject experienced transfusion reaction [mismatched blood transfision] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the transfusion reaction and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [7 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [119 g/L, range = (130 - 175)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 68) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Chronic Ischemic Heart Disease)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 227) the subject was reported with cardiac failure [worsening heart failure] (Grade 4) and on PPD (Day 227) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: is life threatening. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline: normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], and normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 227) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 570) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 569 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amikacin, atorvastatin, cefoperazon, and rifampicin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [9.64 mmol/L, range = (2.14 - 7.14)], high calcium [2.6 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58)], high creatinine [119 umol/L, range = (62 - 106)], high glucose [6.3 mmol/L, range = (4.1 - 5.9)], and high urate [565 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 507), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [27 umol/L, range = (3 - 21), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], high lactate dehydrogenase [263 U/L, range = (5 - 250), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 570) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Other Non-Cardiovascular) (Drowning)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 526) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: aldosterone antagonist, atorvastatin, beta blocker, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high CRP [16.05 mg/L, range = (0 - 3)], high calcium [2.68 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.68 mmol/L, range = (2.1 - 2.58)], high creatinine [112 umol/L, range = (62 - 106)], high glucose [6.3 mmol/L, range = (4.1 - 5.9)], high protein [82 g/L, range = (60 - 80)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 502), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [100 umol/L, range = (62 - 106), BL =high], normal glucose [5.8 mmol/L, range = (4.1 - 5.9), BL =high], and normal urate [387 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 526) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 733) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 25 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [116 U/L, range = (35 - 104)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 680), the subject had the following on-study laboratory test results with results different than baseline:** low glucose [4.4 mmol/L, range = (4.6 - 6.4), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 733) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 624) the subject experienced myocardial infarction. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high glucose [10.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low platelets [126 10^9/L, range = (140 - 450)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.14 mmol/L, range = (2.86 - 8.21), BL =high], normal platelets [160 10^9/L, range = (140 - 450), BL =low], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 624) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DIABETIC HYPERGLYCAEMIC COMA [PPD _PPD _DIABETIC HYPERGLICEMIC COMA_PPD]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Other Non-Cardiovascular) (Diabetes)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included [PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 82) the subject experienced diabetic hyperglycaemic coma [PPD PP PPD _diabetic hyperglicemic coma_PPD] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the diabetic hyperglycaemic coma and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [9-14 /HPF, range = 0-8], high glucose [18.1 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high leukocytes [13-30 /HPF, range = 0-12], high occult blood [1+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 82) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1038) the subject experienced death. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 76 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: cefepim, combined medicine: amoxacyllin+clavulonic acyd, levofloxacyn, and moxifloxacyn.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.9 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], and high glucose [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1038) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history include PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 263) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, ceftriaxone, gatifloxacyn, levofloxacyn, and mropenem.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high creatinine [112 umol/L, range = (62 - 106)], high glucose [9.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-3], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 176), the subject had the following on-study laboratory test results with results different than baseline:** high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], high glucose [1+, range = NEGATIVE, BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 263) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH, CAUSE UNKNOWN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 164) the subject experienced sudden death [sudden death, cause unknown] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 78 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [28.9 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [27 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [13.21 mmol/L, range = (2.86 - 8.21)], high creatinine [210 umol/L, range = (62 - 106)], low erythrocytes [3.7 10^12/L, range = (4 - 5.8)], low hematocrit [0.33 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [103 g/L, range = (130 - 177)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [482 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 86), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.6 mmol/L, range = (4.6 - 6.4), BL =normal], and normal urate [381 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 164) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 100) the subject experienced acute myocardial infarction (Grade 4) and on PPD (Day 101) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 25 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, atorvastatin, beta blocker, ceftriaxonum, clopidogrel, and levofloxacin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [11.78 mmol/L, range = (2.86 - 8.21)], high calcium [2.63 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55)], high creatinine [120 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high glucose [8.2 mmol/L, range = (4.6 - 6.4)], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 100), the subject had the following on-study laboratory test results with results different than baseline:** normal basophils [0.3 %, range = (0 - 2.4), BL = missing], normal basophils [0.02 10^9/L, range = (0 - 0.17), BL = missing], normal calcium [2.23 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.3 mmol/L, range = (2.2 - 2.55), BL =high], high eosinophils [7 %, range = (0 - 6), BL = missing], normal eosinophils [0.41 10^9/L, range = (0 - 0.56), BL = missing], low erythrocytes [3.6 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.32 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [106 g/L, range = (130 - 177), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing], low lymphocytes [7.2 %, range = (15.5 - 46.6), BL = missing], low lymphocytes [0.42 10^9/L, range = (1.02 - 3.36), BL = missing], high monocytes [16.3 %, range = (3.1 - 12.5), BL = missing], high monocytes [0.96 10^9/L, range = (0.18 - 0.9), BL = missing], normal

neutrophils [69.2 %, range = (40.9 - 77), BL = missing], normal neutrophils [4.08 10^9/L, range = (2.03 - 8.36), BL = missing], and normal urate [404 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 101) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 394) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 234 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: amoxiciline, and fluconazole.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.19 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [6.1 mU/L, range = (0.55 - 4.78)], low erythrocytes [3.7 10^12/L, range = (3.8 - 5.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low platelets [120 10^9/L, range = (140 - 450)], high protein [trace, range = NEGATIVE], and high urate [404 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 342), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [122 U/L, range = (35 - 104), BL =normal], high blood urea nitrogen [10.39 mmol/L, range = (2.86 - 8.21), BL =normal], high calcium [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high creatinine [113 umol/L, range = (44 - 80), BL =normal], normal erythrocytes [4.8 10^12/L, range = (3.8 - 5.4), BL =low], high glucose [12.9 mmol/L, range = (4.6 - 6.4), BL =normal], high lactate dehydrogenase [317 U/L, range = (5 - 250), BL =normal], and normal platelets [191 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 394) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL ISCHAEMIA [ISCHEMIC HEART DISEASE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 516) the subject experienced myocardial ischaemia [ischemic heart disease] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial ischaemia and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.96 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [24 mL/min/1.73m2, range = (60 - 9999)], high leukocytes [4-12 /HPF, range = 0-3], high blood urea nitrogen [12.85 mmol/L, range = (2.14 - 7.14)], high creatinine [231 umol/L, range = (62 - 106)], high glucose [12.8 mmol/L, range = (4.1 - 5.9)], high glucose [1+, range = NEGATIVE], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [129 g/L, range = (130 - 175)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], high protein [3+, range = NEGATIVE], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [28 g/L, range = (35 - 52), BL =normal], low calcium [1.7 mmol/L, range = (2.1 - 2.58), BL =normal], low calcium corrected [1.95 mmol/L, range = (2.1 - 2.58), BL =normal], high creatine kinase [616 IU/L, range = (24 - 250), BL =normal], low erythrocytes [3.3 10^12/L, range = (4.1 - 5.9), BL =normal], high leukocytes [12.8 10^9/L, range = (4.1 - 12.3), BL =normal], high magnesium [1.6

mmol/L, range = (0.65 - 1.05), BL =normal], normal potassium [3.9 mmol/L, range = (3.3 - 5.1), BL =high], and low protein [58 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 516) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 673) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 90 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.99 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high calcium [2.85 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.85 mmol/L, range = (2.2 - 2.55)], high glucose [10 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 504), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [124 g/L, range = (130 - 177), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], normal magnesium [0.71 mmol/L, range = (0.65 - 1.05), BL =low], normal protein [negative, range = NEGATIVE, BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 673) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 217) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [17.8 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], high protein [trace, range = NEGATIVE], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 202), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and normal specific gravity [1.03, range = (1 - 1.04), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 217) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 793) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [5.96 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [11.07 mmol/L range = (2.86 - 8.21)], high creatinine [127 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], high glucose [8.5 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [116 g/L, range = (130 - 177)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high potassium [5.3 mmol/L, range = (3.3 - 5.1)], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 678), the subject had the following on-study laboratory test results with results different than baseline:** normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 793) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE CORONARY SYNDROME?, ACUTE HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 941) the subject experienced cardiac failure acute [acute coronary syndrome?, acute heart failure] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: acetylsalicylic acid, amoxicillin, atorvastatin, and beta blocker.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.37 mg/L, range = (0 - 3)], high alanine aminotransferase [42 U/L, range = (4 - 41)], and high glucose [6.9 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 839), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [17 U/L, range = (4 - 41), BL =high], high occult blood [trace, range = NEGATIVE, BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 941) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ISCHAEMIC STROKE [ISCHEMIC STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 302) the subject experienced ischaemic stroke [ischemic stroke] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 24 days after the last dose of any study medication.

Concomitant medications taken at the onset of the ischaemic stroke and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.76 mg/L, range = (0 - 3)], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 302) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 931) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 90 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 841), the subject had the following on-study laboratory test results with results different than baseline:** high platelets [453 10^9/L, range = (140 - 450), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 931) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE DECOMPENSATED HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 190) the subject experienced cardiac failure acute [acute decompensated heart failure] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 94 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [7.13 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatinine [83 umol/L, range = (44 - 80)], high glucose [20.5 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 96), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [32 g/L, range = (35 - 52), BL =normal], high lactate dehydrogenase [293 U/L, range = (5 - 250), BL =normal], and high urate [672 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 190) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GASTRIC CANCER [DEATH FROM GATRIC CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 346) the subject experienced gastric cancer [death from gatric cancer] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 91 days after the last dose of any study medication.

Concomitant medications taken at the onset of the gastric cancer and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.35 mg/L, range = (0 - 3)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** low creatinine [50 umol/L, range = (62 - 106), BL =normal], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5), BL =normal], and low hemoglobin [115 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 346) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 630) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 34 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.07 mg/L, range = (0 - 3)], high occult blood [3+, range = NEGATIVE], high protein [1+, range = NEGATIVE], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 511), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [52 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [55 U/L, range = (4 - 37), BL =normal], high calcium [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9), BL =normal], normal occult blood [negative, range = NEGATIVE, BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 630) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 725) the subject experienced death (Grade 4). The event was considered serious for the following reasons; results in death, and is life threatening. The event occurred 45 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [114 U/L, range = (4 - 41)], high aspartate aminotransferase [38 U/L, range = (4 - 37)], high glucose [7.9 mmol/L, range = (4.1 - 5.9)], high hematocrit [0.56 fraction of 1, range = (0.4 - 0.52)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], and high sodium [149 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 683), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [27 U/L, range = (4 - 37), BL =high], high erythrocytes [6 10^12/L, range = (4.1 - 5.9), BL =normal], high glucose [2+, range = NEGATIVE, BL =normal], high hemoglobin [176 g/L, range = (130 - 175), BL =normal], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06), BL = missing], normal potassium [4.4 mmol/L, range = (3.3 - 5.1), BL =high], high protein [trace, range = NEGATIVE, BL =normal], normal sodium [143 mmol/L, range = (135 - 147), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 725) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PANCREATIC CARCINOMA [PANCREATIC CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 406) the subject experienced pancreatic carcinoma [pancreatic cancer] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 69 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pancreatic carcinoma and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high erythrocytes [6-8 /HPF, range = 0-5], high bilirubin [1+, range = NEGATIVE], high protein [trace, range = NEGATIVE], high protein [81 g/L, range = (60 - 80)], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high CRP [13.78 mg/L, range = (0 - 3), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], normal protein [73 g/L, range = (60 - 80), BL =high], normal specific gravity [1.03, range = (1 - 1.04), BL =high], and high urate [464 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 406) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 623) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 48 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high albumin [53 g/L, range = (35 - 52)], high calcium [2.65 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55)], high creatine kinase [305 IU/L, range = (24 - 160)], high creatinine [82 umol/L, range = (44 - 80)], high hematocrit [0.5 fraction of 1, range = (0.33 - 0.46)], high hemoglobin [163 g/L, range = (110 - 161)], high lactate dehydrogenase [278 U/L, range = (5 - 250)], high protein [85 g/L, range = (60 - 80)], high sodium [148 mmol/L, range = (135 - 147)], and high urate [410 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal albumin [45 g/L, range = (35 - 52), BL =high], normal calcium [2.53 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.53 mmol/L, range = (2.2 - 2.55), BL =high], normal creatinine [77 umol/L, range = (44 - 80), BL =high], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], normal hematocrit [0.44 fraction of 1, range = (0.33 - 0.46), BL =high], normal hemoglobin [149 g/L, range = (110 - 161), BL =high], high occult blood [2+, range = NEGATIVE, BL =normal], and normal protein [75 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 623) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 175) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 16 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [15.66 mg/L, range = (0 - 3)], and low glucose [3.6 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 90), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.3 mmol/L, range = (4.6 - 6.4), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 175) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE CORONARY INSUFFICIENCY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 80) the subject experienced cardiac failure acute [acute coronary insufficiency] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 7 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [58.75 mg/L, range = (0 - 3)], high leukocytes [13-30 /HPF, range = 0-3], high creatinine [109 umol/L, range = (62 - 106)], high occult blood [trace, range = NEGATIVE], and high sodium [150 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 80) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 591) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.52 mg/L, range = (0 - 3)], and low platelets [139 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], and high potassium [5.7 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 591) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 92) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 6 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.93 mg/L, range = (0 - 3)], high erythrocytes [6-8 /HPF, range = 0-5], low glomerular filtration rate, estimated [45 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [106 U/L, range = (4 - 41)], high aspartate aminotransferase [54 U/L, range = (4 - 37)], high creatinine [145 umol/L, range = (62 - 106)], high glucose [7.8 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 86), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [32 U/L, range = (4 - 37), BL =high].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 92) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 379) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 308 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [89.28 mg/L, range = (0 - 3)], low erythrocytes [3.5 10^12/L, range = (4.1 - 5.9)], low glucose [4.2 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.27 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [83 g/L, range = (130 - 175)], and high platelets [521 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 379) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): COMA [CEREBRAL COMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Neurological)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 379) the subject experienced coma [cerebral coma] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 14 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the coma and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [565 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 334), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [43 U/L, range = (4 - 41), BL =normal], low creatinine [57 umol/L, range = (62 - 106), BL =normal], high glucose [7.3 mmol/L, range = (4.6 - 6.4), BL =normal], high glucose [1+, range = NEGATIVE, BL =normal], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06), BL =normal], low platelets [118 10^9/L, range = (140 - 450), BL =normal], normal potassium [4.5 mmol/L, range = (3.3 - 5.1), BL =high], high protein [trace, range = NEGATIVE, BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 379) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 251) the subject experienced death [unknown cause of death] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.73 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [6.42 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [136 U/L, range = (40 - 129)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], and high creatinine [164 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [114 U/L, range = (40 - 129), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 251) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): INJURY [TRAUMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 654) the subject experienced injury [trauma] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 60 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the injury and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], low glucose [3.2 mmol/L, range = (4.6 - 6.4)], high protein [3+, range = NEGATIVE], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 519), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high blood urea nitrogen [8.71 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [122 umol/L, range = (62 - 106), BL =normal], high glucose [16 mmol/L, range = (4.6 - 6.4), BL =low], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06), BL =normal], and low leukocytes [4 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 654) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH UNASCERTAINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 515) the subject experienced death [death unascertained] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 471 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, aldosterone antagonist, angiotensin receptor blocker, atorvastatin, beta blocker, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.99 mg/L, range = (0 - 3)], high glucose [13.3 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], high protein [3+, range = NEGATIVE], and high urate [381 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], normal glucose [negative, range = NEGATIVE, BL =high], and high occult blood [3+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 515) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL ISCHAEMIA [CHRONIC ISCHEMIC HEART DISEASE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 662) the subject experienced myocardial ischaemia [chronic ischemic heart disease]. The event was considered serious for the following reasons: results in death. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial ischaemia and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.71 mg/L, range = (0 - 3)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 504), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [24 umol/L, range = (3 - 21), BL =normal], high erythrocytes [9-14 /HPF, range = 0-5, BL = missing], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], high occult blood [trace, range = NEGATIVE, BL =normal], and high sodium [148 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 662) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 643) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.85 mmol/L, range = (2.86 - 8.21)], high creatine kinase [218 IU/L, range = (20 - 203)], high creatinine [130 umol/L, range = (62 - 106)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high leukocytes [13-30 /HPF, range = 0-3], high occult blood [trace, range = NEGATIVE], high potassium [5.9 mmol/L, range = (3.3 - 5.1)], high protein [1+, range = NEGATIVE], and high urate [535 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 558), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [126 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 643) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 779) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.66 mg/L, range = (0 - 3)], high alkaline phosphatase [132 U/L, range = (40 - 129)], high aspartate aminotransferase [43 U/L, range = (4 - 37)], high creatine kinase [848 IU/L, range = (24 - 250)], high glucose [6.6 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 699), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [96 U/L, range = (40 - 129), BL =high], normal aspartate aminotransferase [12 U/L, range = (4 - 37), BL =high], high bilirubin [2+, range = NEGATIVE, BL =normal], high calcium [2.59 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], normal creatine kinase [85 IU/L, range = (24 - 250), BL =high], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 779) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 319) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4 mg/L, range = (0 - 3)], high glucose [7.1 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 319) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE [HEART FAILURE, UNSPECIFIED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 57) the subject experienced cardiac failure [heart failure, unspecified] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 13 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure and up to 30 days prior to event onset included: ACE inhibitor, atorvastatin, and glycemic control medication.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.43 mg/L, range = (0 - 3)], high creatinine [85 umol/L, range = (44 - 80)], high glucose [13.8 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 57) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 673) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 588 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, analgesic or antipyretic agent, angiotensin receptor blocker, atorvastatin, beta blocker, doxycycline, heparin, nitrofurantoin, and oral corticosteroids.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [22 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 673) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). In PPD, the subject was diagnosed with myeloma. On PPD, the subject was admitted to the hospital with peripheral neuropathy secondary to chemotherapy for multiple myeloma, debilitation and recurrent falls. On PPD the subject was hospitalized with rhabdomyolysis, confusion and suspected sepsis. On PPD (Day 591) the subject died. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 240 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acyclovir, amoxicillin, analgesic or antipyretic agent, antidepressants, atorvastatin, clarithromycin, enoxaparin, gentamycin, oral corticosteroids, and tazocin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [42 U/L, range = (4 - 41)], and low magnesium [0.6 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal alanine aminotransferase [34 U/L, range = (4 - 41), BL =high], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 591) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CENTRAL NERVOUS SYSTEM LESION [BRAIN LESION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 456) the subject experienced central nervous system lesion [brain lesion]. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 231 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the central nervous system lesion and up to 30 days prior to event onset included: atorvastatin, fenofibrate, and penicillen.

The subject had the following abnormal laboratory test results at baseline: high creatinine [110 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high glucose [8.6 mmol/L, range = (4.6 - 6.4)], and low hemoglobin [127 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [86 umol/L, range = (62 - 106), BL =high], and normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 456) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SHOCK HAEMORRHAGIC [HAEMORRHAGIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 132) the subject experienced shock haemorrhagic [haemorrhagic shock] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the shock haemorrhagic and up to 30 days prior to event onset included: ACE inhibitor, aldosterone antagonist, analgesic or antipyretic agent, atorvastatin, beta blocker, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.17 mg/L, range = (0 - 3)], and high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 120), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.5 mmol/L, range = (2.86 - 8.21), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 132) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 146) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 64 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin, and terbafine tablets.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high aspartate aminotransferase [38 U/L, range = (4 - 37)], high creatine kinase [219 IU/L, range = (20 - 203)], high creatinine [115 umol/L, range = (62 - 106)], and low hemoglobin [129 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 82), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21), BL =normal], and low glucose [4.4 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 146) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 549) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, clotrimazole 1% cream, and flamazine cream [silver sulfadiazine].

The subject had the following abnormal laboratory test results at baseline: high CRP [32.4 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [40 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [14.28 mmol/L, range = (2.86 - 8.21)], high creatinine [127 umol/L, range = (62 - 106)], low erythrocytes [3.4 10^12/L, range = (4 - 5.8)], high glucose [7.1 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.27 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [89 g/L, range = (130 - 177)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [702 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 502), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [132 U/L, range = (40 - 129), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 549) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIO-RESPIRATORY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 438) the subject experienced cardio-respiratory arrest. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 17 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, clopidogrel, doxycycline, doxycycline 200mg for 1 day only reduced to 100mg od PPD, and tobradex.

The subject had the following abnormal laboratory test results at baseline: high urate [393 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [232 IU/L, range = (24 - 160), BL =normal], high creatinine [84 umol/L, range = (44 - 80), BL =normal], low hemoglobin [104 g/L, range = (110 - 161), BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 438) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 290) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 79 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 167), the subject had the following on-study laboratory test results with results different than baseline: high lactate dehydrogenase [304 U/L, range = (5 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 290) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 789) the subject experienced pneumonia aspiration [aspiration pneumonia] (Grade 4) and on PPD (Day 818) the subject died due to pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 646 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: atorvastatin, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high leukocytes [4-12 /HPF, range = 0-3], low platelets [110 10^9/L, range = (140 - 450)], high protein [1+, range = NEGATIVE], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 172), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high hematocrit [0.53 fraction of 1, range = (0.4 - 0.52), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], normal platelets [145 10^9/L, range = (140 - 450), BL =low], normal protein [negative, range = NEGATIVE, BL =high], and normal urate [404 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 818) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 850) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, and metronidazole.

The subject had the following abnormal laboratory test results at baseline: high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** normal protein [negative, range = NEGATIVE, BL =high], and low sodium [131 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 850) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 178) the subject experienced metastases to pleura [pleural metastases t3 n2 m1a] (Grade 3) and on PPD (Day 207) the subject experienced lung adenocarcinoma [non small cell lung cancer adenocarcinoma right lung] (Grade 3). On PPD (Day 355) the subject died. The event was considered serious for the following reasons: results in death. The event occurred 186 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.37 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high creatinine [95 umol/L, range = (44 - 80)], high lactate dehydrogenase [289 U/L, range = (5 - 250)], and high urate [351 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], and normal lactate dehydrogenase [247 U/L, range = (5 - 250), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 355) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PROSTATE CANCER METASTATIC [DEATH DUE TO TERMINAL METASTATIC HIGH GRADE PROSTATE CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 968) the subject experienced prostate cancer metastatic [terminal metastatic high grade prostate cancer] (Grade 4) and on PPD (Day 992) the subject died due to the event. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 361 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the prostate cancer metastatic and up to 30 days prior to event onset included: atorvastatin, fucidin, and nystatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.29 mg/L, range = (0 - 3)], low hemoglobin [128 g/L, range = (130 - 177)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 503), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [152 U/L, range = (40 - 129), BL =normal], high lactate dehydrogenase [724 U/L, range = (5 - 250), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and high urate [529 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 992) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 201) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 74 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, glycemic control medication, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [23 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [140 U/L, range = (40 - 129)], high blood urea nitrogen [13.92 mmol/L, range = (2.86 - 8.21)], high creatinine [235 umol/L, range = (62 - 106)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], low hemoglobin [129 g/L, range = (130 - 177)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 201) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ADENOCARCINOMA GASTRIC [METASTATIC HER2 POSITIVE ADENOCARCINOMA OF THE STOMACH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 614) the subject experienced adenocarcinoma gastric [metastatic her2 positive adenocarcinoma of the stomach] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 109 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the adenocarcinoma gastric and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low thyrotropin [0.48 mU/L, range = (0.55 - 4.78)], high bilirubin [1+, range = NEGATIVE], low hemoglobin [126 g/L, range = (130 - 177)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], high protein [1+, range = NEGATIVE], and high specific gravity [>1.045]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 614) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY FIBROSIS [PULMONARY FIBROSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 760) the subject experienced pulmonary fibrosis (Grade 3). The event was considered serious for the following reasons: results in death. The event occurred 87 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary fibrosis and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [12.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], and high urate [541 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high blood urea nitrogen [8.6 mmol/L, range = (2.86 - 8.21), BL =normal], high direct bilirubin [8 umol/L, range = (0 - 5), BL =normal], normal glucose [5.1 mmol/L, range = (4.6 - 6.4), BL =high], high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high], and high sodium [148 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 760) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): VENTRICULAR FAILURE ['1A LEFT VENTRICULAR FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 907) the subject experienced ventricular failure ['1a left ventricular failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 61 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the ventricular failure and up to 30 days prior to event onset included: aciclovir, amoxicillin, atorvastatin, and flucloxacillin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.47 mg/L, range = (0 - 3)], high alkaline phosphatase [153 U/L, range = (40 - 129)], and low glucose [4.5 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 846), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [98 U/L, range = (40 - 129), BL =high], high aspartate aminotransferase [44 U/L, range = (4 - 37), BL =normal], high bilirubin [1+, range = NEGATIVE, BL =normal], normal glucose [5.6 mmol/L, range = (4.6 - 6.4), BL =low], low hemoglobin [127 g/L, range = (130 - 177), BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 907) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL ISCHAEMIA [ISCHEMIC HEART DISEASE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 306) the subject experienced myocardial ischaemia [ischemic heart disease] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 53 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial ischaemia and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** low hemoglobin [129 g/L, range = (130 - 177), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 306) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 928) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [9.93 mU/L, range = (0.55 - 4.78)], high creatine kinase [208 IU/L, range = (20 - 203)], high creatinine [119 umol/L, range = (62 - 106)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 840), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [194 IU/L, range = (20 - 203), BL =high], normal creatinine [97 umol/L, range = (62 - 106), BL =high], normal urate [357 umol/L, range = (202 - 416), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 928) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): METASTATIC SQUAMOUS CELL CARCINOMA [METASTATIC SQUAMOUS CELL CARCINOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 488) the subject experienced metastatic squamous cell carcinoma (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 167 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [250 IU/L, range = (20 - 203)], high glucose [7.4 mmol/L, range = (4.6 - 6.4)], and low platelets [116 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 321), the subject had the following on-study laboratory test results with results different than baseline:** high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal platelets [167 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 488) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MESOTHELIOMA MALIGNANT [MESOTHELIOMA MALIGNANT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 374) the subject experienced mesothelioma malignant (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 51 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the mesothelioma malignant and up to 30 days prior to event onset included: clarithromycin 500ng, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [141 umol/L, range = (62 - 106)], and high urate [458 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 163), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 374) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): GASTROINTESTINAL HAEMORRHAGE [GASTRO INTESTINAL BLEED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 537) the subject experienced gastrointestinal haemorrhage [gastro intestinal bleed] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gastrointestinal haemorrhage and up to 30 days prior to event onset included: atorvastatin, and over the counter omega-3 fish oil.

The subject had the following abnormal laboratory test results at baseline: high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 504), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [333 IU/L, range = (20 - 203), BL =normal], low glucose [4.4 mmol/L, range = (4.6 - 6.4), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 537) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL FIBROSIS [MYOCARDIAL FIBROSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 68) the subject experienced myocardial fibrosis (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial fibrosis and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.08 mg/L, range = (0 - 3)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high protein [trace, range = NEGATIVE], high specific gravity [1.04, range = (1 - 1.04)], and low urate [184 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 68) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 411) the subject experienced pneumonia (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and other medically important serious event. The event occurred 39 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: amoxicillin, amoxicillin 500 mg, amoxicillin 500mg, atorvastatin, and azithromycin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high CRP [5.98 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], low glucose [4.4 mmol/L, range = (4.6 - 6.4)], low hemoglobin [122 g/L, range = (130 - 177)], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 358), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.43 mmol/L, range = (2.86 - 8.21), BL =high], high creatinine [108 umol/L, range = (62 - 106), BL =normal], normal glucose [4.7 mmol/L, range = (4.6 - 6.4), BL =low], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], high lactate dehydrogenase [289 U/L, range = (5 - 250), BL =normal], high leukocytes [12.8 10^9/L, range = (4.1 - 12.3), BL =normal], low sodium [133 mmol/L, range = (135 - 147), BL =normal], and normal urate [339 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 411) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 823) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high CRP [4.56 mg/L, range = (0 - 3)], high creatine kinase [392 IU/L, range = (20 - 203)], high creatinine [141 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high protein [1+, range = NEGATIVE], and high urate [422 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 674), the subject had the following on-study laboratory test results with results different than baseline:** high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], and normal urate [404 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 823) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 229) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 200 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and penicillin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [115 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], and low hemoglobin [126 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 190), the subject had the following on-study laboratory test results with results different than baseline:** normal cytomegalovirus IgG antibody [negative, range = NEGATIVE, BL = missing], normal cytomegalovirus IgM antibody [negative, range = NEGATIVE, BL = missing], high Epstein-Barr capsid IgG antibody [positive, range = NEGATIVE, BL = missing], normal Epstein-Barr capsid IgM antibody [negative, range = NEGATIVE, BL = missing], high Epstein-Barr early antigen [positive, range = NEGATIVE, BL = missing], high Epstein-Barr nuclear antibody [positive, range = NEGATIVE, BL = missing], normal hepatitis A virus IgM antibody [indeterminate, range = NEGATIVE, BL = missing], high hepatitis A virus surface antibody [positive, range = NEGATIVE, BL = missing], normal hepatitis B virus core antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus core IgM antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus surface antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus surface antigen [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus e antigen [negative, range = NEGATIVE, BL = missing], normal hepatitis C virus antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis D virus antibody [negative, range = NEGATIVE,

BL = missing], normal hepatitis E virus IgG antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis E virus IgM antibody [negative, range = NEGATIVE, BL = missing], high herpes simplex virus 1/2 IgG antibody [positive, range = NEGATIVE, BL = missing], normal herpes simplex virus 1/2 IgM antibody [negative, range = NEGATIVE, BL = missing], high prothrombin intl. normalized ratio [2.37, range = (0.5 - 1.5), BL = missing], and high prothrombin time [25.3 sec, range = (9.4 - 12.5), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 229) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): AORTIC ANEURYSM RUPTURE [RUPTURED ABDOMINAL AORTIC ANEURYSM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 404) the subject experienced aortic aneurysm rupture [ruptured abdominal aortic aneurysm] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the aortic aneurysm rupture and up to 30 days prior to event onset included: atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 330), the subject had the following on-study laboratory test results with results different than baseline: normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 404) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): BLADDER CANCER [BLADDER CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 173) the subject experienced bladder cancer (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 89 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the bladder cancer and up to 30 days prior to event onset included: simvastatin, and trimethoprim.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.15 mg/L, range = (0 - 3)], high erythrocytes [31-50 /HPF, range = 0-5], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-3], high occult blood [3+, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 173) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUBARACHNOID HAEMORRHAGE [SUBARACHNOID HAEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 550) the subject experienced subarachnoid haemorrhage (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the subarachnoid haemorrhage and up to 30 days prior to event onset included: amoxicillin, atorvastatin, augmentin, clarithromycin, co-amoxiclav, and doxycycline.

The subject had the following abnormal laboratory test results at baseline: high CRP [18.17 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high creatinine [131 umol/L, range = (62 - 106)], low hemoglobin [126 g/L, range = (130 - 177)], high protein [trace, range = NEGATIVE], and high urate [577 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal hemoglobin [137 g/L, range = (130 - 177), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 550) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GLIOBLASTOMA [GLIOBLASTOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 766) the subject experienced glioblastoma. The event was considered serious for the following reasons: results in death. The event occurred 100 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the glioblastoma and up to 30 days prior to event onset included: amoxicillin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.76 mg/L, range = (0 - 3)], low glucose [4.3 mmol/L, range = (4.6 - 6.4)], and high urate [571 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 680), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [43 U/L, range = (4 - 41), BL =normal], high bilirubin [1+, range = NEGATIVE, BL =normal], high blood urea nitrogen [14.53 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [111 umol/L, range = (62 - 106), BL =normal], high leukocytes [12.9 10^9/L, range = (4.1 - 12.3), BL =normal], and normal urate [399 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 766) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG NEOPLASM MALIGNANT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 227) the subject experienced lung neoplasm malignant (Grade 3). The event was considered serious for the following reasons: results in death. The event occurred 58 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: amoxicillin, atorvastatin, co-amoxiclav, and phenoxymethylpenicillin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [115 U/L, range = (35 - 104)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 179), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [41 U/L, range = (4 - 33), BL =normal], high glucose [7.7 mmol/L, range = (4.6 - 6.4), BL =normal], and high lactate dehydrogenase [375 U/L, range = (5 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 227) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 156) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 71 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.15 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [24 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [106 U/L, range = (35 - 104)], high blood urea nitrogen [22.13 mmol/L, range = (2.14 - 7.14)], high creatinine [175 umol/L, range = (44 - 80)], high glucose [8.7 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [288 U/L, range = (5 - 250)], high potassium [5.8 mmol/L, range = (3.3 - 5.1)], and high urate [523 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [99 U/L, range = (35 - 104), BL =high], low glucose [<2.2 mmol/L, BL =high], and low hemoglobin [114 g/L, range = (116 - 162), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 156) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA [BRONCHOPNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 682) the subject experienced pneumonia [bronchopneumonia] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 184 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: ACE inhibitor, amoxicillin, analgesic or antipyretic agent, antidepressants, atorvastatin, simvastatin, and trimethoprin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.22 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high creatinine [115 umol/L, range = (62 - 106)], low hemoglobin [125 g/L, range = (130 - 177)], and low protein [59 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 682) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH OF UNKNOWN CAUSE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 335) the subject experienced sudden death [sudden death of unknown cause] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.7 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 333), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.71 mmol/L, range = (2.86 - 8.21), BL =normal], high CRP [11.71 mg/L, range = (0 - 3), BL =normal], high creatine kinase [278 IU/L, range = (24 - 250), BL =normal], and low hemoglobin [128 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 335) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PULMONARY EMBOLISM [PULMONARY EMBOLISM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 676) the subject experienced pulmonary embolism (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 2 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary embolism and up to 30 days prior to event onset included: ACE inhibitor, analgesic or antipyretic agent, atorvastatin, dipyridamole, and ezetimibe.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 674), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 676) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 228) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 58 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [24 umol/L, range = (3 - 21), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 228) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 614) the subject experienced acute kidney injury (Grade 4) and pneumonia [left basal pneumonia] (Grade 4). On PPD (Day 618) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 136 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.66 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [22 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [16.78 mmol/L, range = (2.86 - 8.21)], high calcium [2.7 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.7 mmol/L, range = (2.2 - 2.55)], high creatine kinase [180 IU/L, range = (24 - 160)], and high creatinine [194 umol/L, range = (44 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [152 IU/L, range = (24 - 160), BL =high], high glucose [9.2 mmol/L, range = (4.6 - 6.4), BL =normal], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 618) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE HEPATIC FAILURE [ACUTE LIVER FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Hepatobiliary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 177) the subject experienced acute hepatic failure [acute liver failure] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. On an unknown date in PPD the subject was diagnosed with bacterial peritonitis; on PPD the subject was hospitalized with acute liver failure. On PPD the subject died from spontaneous bacterial peritonitis and acute liver failure. The event occurred 149 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute hepatic failure and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [24.86 mg/L, range = (0 - 3)], high erythrocytes [15-30 /HPF, range = 0-5], low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], low albumin [32 g/L, range = (35 - 52)], high bilirubin [22 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [166 umol/L, range = (62 - 106)], high direct bilirubin [9 umol/L, range = (0 - 5)], high glucose [11.4 mmol/L, range = (4.6 - 6.4)], high glucose [1+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [294 U/L, range = (5 - 250)], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [2+, range = NEGATIVE], low platelets [110 10^9/L, range = (140 - 450)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 177) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [RESPIRATION FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 217) the subject experienced respiratory failure [respiration failure] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 130 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: azithromycin, diflucan, fenofibrate, flagyl, rosuvastatin, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.81 mg/L, range = (0 - 3)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.37 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [120 g/L, range = (130 - 177)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 217) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 829) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 407 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, augmentin, cipro, mycelex troche, and zithromax.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.01 mg/L, range = (0 - 3)], high erythrocytes [6-8 /HPF, range = 0-5], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], and low hemoglobin [129 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [1.08 mg/L, range = (0 - 3), BL =high], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 829) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 671) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 79 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: atorvastatin, and cipro.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [95 umol/L, range = (44 - 80)], low protein [59 g/L, range = (60 - 80)], and high urate [470 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 508), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [8.21 mmol/L, range = (2.86 - 8.21), BL =high], low glucose [4.2 mmol/L, range = (4.6 - 6.4), BL =normal], and low platelets [125 10^9/L, range = (140 - 450), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 671) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 338) the subject experienced death [death nos]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 255 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [115 U/L, range = (35 - 104)], high CRP [15.91 mg/L, range = (0 - 3)], high creatinine [93 umol/L, range = (44 - 80)], and high sodium [149 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 83), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [96 U/L, range = (35 - 104), BL =high], high creatine kinase [277 IU/L, range = (24 - 160), BL =normal], and normal sodium [144 mmol/L, range = (135 - 147), BL =high].

Action taken with IP was dose not changed. The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 338) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 252) the subject experienced lung neoplasm malignant [lung cancer] (Grade 4) and on PPD (Day 617) the subject died due to the event. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 587 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.31 mg/L, range = (0 - 3)], high creatine kinase [415 IU/L, range = (24 - 250)], high glucose [9.5 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [128 g/L, range = (130 - 175)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.55 mmol/L, range = (0.65 - 1.05)], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

Action taken with IP and statin was not reported.The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 617) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): AORTIC STENOSIS [AORTIC STENOSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 248) the subject experienced aortic stenosis (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the aortic stenosis and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.71 mg/L, range = (0 - 3)], high lactate dehydrogenase [276 U/L, range = (5 - 250)], and high potassium [5.4 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [114 umol/L, range = (62 - 106), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [115 g/L, range = (130 - 177), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 248) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 12) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, fenofibrate, simvastatin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high creatinine [108 umol/L, range = (62 - 106)], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 12) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBRAL HAEMORRHAGE [CEREBRAL HEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 343) the subject experienced cerebral haemorrhage [cerebral hemorrhage] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and requires or prolongs hospitalization. The event occurred 27 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebral haemorrhage and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, analgesic or antipyretic agent, atorvastatin, beta blocker, ezetimibe, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.14 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [47 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], high creatinine [119 umol/L, range = (62 - 106)], low HbA1c [0.04 fraction of 1, range = (0.04 - 0.06)], low platelets [112 10^9/L, range = (140 - 450)], high potassium [5.9 mmol/L, range = (3.3 - 5.1)], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 330), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.25 mmol/L, range = (2.86 - 8.21), BL =high], normal CRP [1.25 mg/L, range = (0 - 3), BL =high], and normal HbA1c [0.04 fraction of 1, range = (0.04 - 0.06), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 343) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIOVASCULAR DISORDER [CARDIOVASCULAR DISORDER NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 147) the subject experienced cardiovascular disorder [cardiovascular disorder nos] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 62 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiovascular disorder and up to 30 days prior to event onset included: fenofibrate, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.81 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [40 mL/min/1.73m2, range = (60 - 9999)], high creatinine [155 umol/L, range = (62 - 106)], high glucose [10.9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21), BL =normal], high creatine kinase [296 IU/L, range = (24 - 250), BL =normal], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52), BL =normal], and low hemoglobin [129 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 147) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA ASPIRATION [ASPIRATION PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 45) the subject experienced pneumonia aspiration [aspiration pneumonia] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pneumonia aspiration and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, antidepressants, beta blocker, glycemic control medication, insulin, over the counter omega-3 fish oil, simvastatin, vitamin supplements, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high CRP [20.98 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [169 U/L, range = (40 - 129)], high creatinine [118 umol/L, range = (62 - 106)], high erythrocytes [tntc /HPF, range = 0-5], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [2+, range = NEGATIVE], high protein [2+, range = NEGATIVE], and high urate [470 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 45) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): BRONCHITIS [BRONCHIAL INFECTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 197) the subject experienced bronchitis [bronchial infection] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 23 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the bronchitis and up to 30 days prior to event onset included: analgesic or antipyretic agent, antidepressants, atorvastatin, clopidogrel, hormone replacement therapy, over the counter omega-3 fish oil, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.07 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high calcium [2.65 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55)], high creatinine [128 umol/L, range = (44 - 80)], high glucose [6.6 mmol/L, range = (4.6 - 6.4)], and high lactate dehydrogenase [256 U/L, range = (5 - 250)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 174), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.53 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.53 mmol/L, range = (2.2 - 2.55), BL =high], normal glucose [5.4 mmol/L, range = (4.6 - 6.4), BL =high], and normal lactate dehydrogenase [219 U/L, range = (5 - 250), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 197) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 556) the subject experienced death [death nos]. The event was considered serious for the following reasons: results in death. The event occurred 541 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [135 U/L, range = (40 - 129)], high creatinine [112 umol/L, range = (62 - 106)], low hemoglobin [126 g/L, range = (130 - 177)], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 556) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 601) the subject experienced cardiac arrest. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, is life threatening, and other medically important serious event. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: cefadroxil, ezetimibe, fenofibrate, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], low alkaline phosphatase [36 U/L, range = (40 - 129)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [40 U/L, range = (40 - 129), BL =low], and high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 601) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 835) the subject experienced death (Grade 3). The event was considered serious for the following reasons; results in death, and is life threatening. The event occurred 329 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.15 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [157 U/L, range = (40 - 129)], high calcium [2.6 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58)], high creatinine [148 umol/L, range = (62 - 106)], and high urate [476 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal calcium [2.55 mmol/L, range = (2.1 - 2.58), BL =high], normal calcium corrected [2.58 mmol/L, range = (2.1 - 2.58), BL =high], high glucose [7 mmol/L, range = (4.1 - 5.9), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high protein [2+, range = NEGATIVE, BL =normal], and normal urate [291 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 835) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 760) the subject experienced death [death nos] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 88 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [13.69 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], high protein [trace, range = NEGATIVE], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 672), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], normal blood urea nitrogen [5.32 mmol/L, range = (2.86 - 8.21), BL =high], and normal urate [345 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 760) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 971) the subject experienced death [death nos]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 970 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [106 U/L, range = (35 - 104)], high CRP [18.98 mg/L, range = (0 - 3)], high glucose [7.2 mmol/L, range = (4.6 - 6.4)], and high urate [375 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 34), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [88 U/L, range = (35 - 104), BL =high], normal basophils [0.2 %, range = (0 - 2.4), BL = missing], normal basophils [0.02 10^9/L, range = (0 - 0.17), BL = missing], low calcium [2 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2 mmol/L, range = (2.2 - 2.55), BL =normal], normal choriogonadotropin beta [negative, range = NEGATIVE, BL = missing], high creatine kinase [190 IU/L, range = (24 - 160), BL =normal], high eosinophils [5.5 %, range = (0 - 6), BL = missing], high eosinophils [0.61 10^9/L, range = (0 - 0.56), BL = missing], high erythrocytes [6.3 10^12/L, range = (3.8 - 5.4), BL =normal], normal follicle stimulating hormone [24.2 IU/L, range = (23 - 116.3), BL = missing], high hematocrit [0.57 fraction of 1, range = (0.33 - 0.46), BL =normal], high hemoglobin [187 g/L, range = (110 - 161), BL =normal], normal HbA1c [0.08 fraction of 1, range = (0.04 - 0.06), BL = missing], normal hepatitis A virus IgM antibody [negative, range = NEGATIVE, BL = missing], high hepatitis A virus surface antibody [positive, range = NEGATIVE, BL = missing], normal hepatitis B virus core antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus core IgM antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus surface antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus

surface antigen [negative, range = NEGATIVE, BL = missing], normal hepatitis B virus e antigen [negative, range = NEGATIVE, BL = missing], normal hepatitis C virus antibody [negative, range = NEGATIVE, BL = missing], normal hepatitis D virus antibody [negative, range = NEGATIVE, BL = missing], normal lymphocytes [44.7 %, range = (15.5 - 46.6), BL = missing], high lymphocytes [4.96 10^9/L, range = (1.02 - 3.36), BL = missing], low monocytes [1 %, range = (3.1 - 12.5), BL = missing], low monocytes [0.11 10^9/L, range = (0.18 - 0.9), BL = missing], normal neutrophils [48.6 %, range = (40.9 - 77), BL = missing], and normal n.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 971).

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 986) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 18 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.67 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high creatinine [109 umol/L, range = (62 - 106)], high erythrocytes [15-30 /HPF, range = 0-5], and high occult blood [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 842), the subject had the following on-study laboratory test results with results different than baseline:** low bilirubin [2 umol/L, range = (3 - 21), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], high glucose [6.7 mmol/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [117 g/L, range = (130 - 175), BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 986) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 134) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 44 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [16.69 mg/L, range = (0 - 3)], high hepatitis C virus antibody [positive, range = NEGATIVE], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], and low hemoglobin [128 g/L, range = (130 - 175)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 90), the subject had the following on-study laboratory test results with results different than baseline:** low bilirubin [2 umol/L, range = (3 - 21), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 134) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 470) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 25 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: amoxicillin, niacin extended-release (> 200 mg/day only), over the counter omega-3 fish oil, simvastatin, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high creatinine [153 umol/L, range = (62 - 106)], low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], high glucose [7.9 mmol/L, range = (4.6 - 6.4)], high protein [trace, range = NEGATIVE], low thyrotropin [0.25 mU/L, range = (0.55 - 4.78)], high urate [535 umol/L, range = (202 - 416)], and low hemoglobin [123 g/L, range = (130 - 177)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [4.16 mg/L, range = (0 - 3), BL =normal], and normal protein [negative, range = NEGATIVE,

BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 470) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIOPULMONARY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 479) the subject experienced cardio-respiratory arrest [cardiopulmonary arrest] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 354 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: atorvastatin, tamiflu, and zithromax.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.91 mg/L, range = (0 - 3)], high alkaline phosphatase [112 U/L, range = (35 - 104)], high creatinine [95 umol/L, range = (44 - 80)], high glucose [10.5 mmol/L, range = (4.6 - 6.4)], high leukocytes [31-50 /HPF, range = 0-12], high protein [trace, range = NEGATIVE], low protein [59 g/L, range = (60 - 80)], and high urate [577 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 185), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high calcium [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], high creatine kinase [520 IU/L, range = (24 - 170), BL =normal], high glucose [3+, range = NEGATIVE, BL =normal], normal protein [negative, range = NEGATIVE, BL =high], normal protein [68 g/L, range = (60 - 80), BL =low], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 479) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ASPIRATION TRACHEAL [ASPIRATION TRACHEAL]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 5) the subject experienced aspiration tracheal (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the aspiration tracheal and up to 30 days prior to event onset included: atorvastatin, and clopidogrel.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 5) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 587) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 76 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], high creatinine [110 umol/L, range = (62 - 106)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], low glucose [4.1 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [111 g/L, range = (130 - 177)], high leukocytes [4-12 /HPF, range = 0-3], and high urate [434 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 511), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], high blood urea nitrogen [14.64 mmol/L, range = (2.86 - 8.21), BL =normal], normal glucose [5.5 mmol/L, range = (4.6 - 6.4), BL =low], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and high protein [1+, range = NEGATIVE, BL =normal].

Action taken with IP was dose not changed. The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 587) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): COMPLETED SUICIDE [SUICIDE PPD)]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Suicide)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 126) the subject experienced completed suicide [suicide (PPD)] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the completed suicide and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, rivaroxaban, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [16.93 mg/L, range = (0 - 3)], high creatinine [118 umol/L, range = (62 - 106)], high platelets [467 10^9/L, range = (140 - 450)], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], and low sodium [134 mmol/L, range = (135 - 147)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 101), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [98 umol/L, range = (62 - 106), BL =high], normal platelets [435 10^9/L, range = (140 - 450), BL =high], and normal sodium [135 mmol/L, range = (135 - 147), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 126) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUBDURAL HAEMATOMA [SUBDURAL HAEMATOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 507) the subject experienced subdural haematoma (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 83 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the subdural haematoma and up to 30 days prior to event onset included: atorvastatin, ciprofloxacin, and flagyl.

The subject had the following abnormal laboratory test results at baseline: high CRP [20.32 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high alanine aminotransferase [35 U/L, range = (4 - 33)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [100 umol/L, range = (44 - 80)], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.4)], high lactate dehydrogenase [349 U/L, range = (5 - 250)], and high urate [476 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 340), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [0.25 mg/L, range = (0 - 3), BL =high], normal erythrocytes [4 10^12/L, range = (3.8 - 5.4), BL =low], high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 507) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): METASTATIC MALIGNANT MELANOMA [METASTATIC MELANOMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 293) the subject experienced metastatic malignant melanoma [worsening metastatic melanoma] (Grade 4) and on PPD (Day 353) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 113 days after the last dose of any study medication.

Concomitant medications taken at the onset of the metastatic malignant melanoma and up to 30 days prior to event onset included: atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 353) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 626) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 611 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.66 mg/L, range = (0 - 3)], high alkaline phosphatase [114 U/L, range = (35 - 104)], high calcium [2.8 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.83 mmol/L, range = (2.1 - 2.58)], high creatinine [89 umol/L, range = (44 - 80)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], and high urate [446 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 626) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 639) the subject experienced death. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 42 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, levofloxacin, and macrobid.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high creatinine [87 umol/L, range = (44 - 80)], high glucose [7.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-12], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 526), the subject had the following on-study laboratory test results with results different than baseline:** low creatine kinase [22 IU/L, range = (24 - 160), BL =normal], normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], normal leukocytes [4-12 /HPF, range = 0-12, BL =high], low magnesium [0.6 mmol/L, range = (0.65 - 1.05), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and high urate [399 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 639) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CIRCULATORY COLLAPSE [CARDIOVASCULAR COLLAPSE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 480) the subject experienced circulatory collapse [cardiovascular collapse] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 59 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the circulatory collapse and up to 30 days prior to event onset included: augmentin, cefazolin, fenofibrate, over the counter omega-3 fish oil, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [38 mL/min/1.73m2, range = (60 - 9999)], low albumin [33 g/L, range = (35 - 52)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [158 umol/L, range = (62 - 106)], high glucose [13.9 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [1+, range = NEGATIVE], high protein [3+, range = NEGATIVE], and low protein [54 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal albumin [35 g/L, range = (35 - 52), BL =low], low erythrocytes [3.4 10^12/L, range = (4 - 5.8), BL =normal], high erythrocytes [tntc /HPF, range = 0-5, BL =normal], low hematocrit [0.32 fraction of 1, range = (0.37 - 0.5), BL =normal], and low hemoglobin [102 g/L, range = (130 - 177), BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 480) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 158) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 58 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.17 mg/L, range = (0 - 3)], high blood urea nitrogen [11.07 mmol/L, range = (2.86 - 8.21)], high creatinine [171 umol/L, range = (44 - 80)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], and high urate [601 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 100), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.07 mmol/L, range = (2.86 - 8.21), BL =high], high creatine kinase [163 IU/L, range = (24 - 160), BL =normal], normal potassium [4.6 mmol/L, range = (3.3 - 5.1), BL =high], and high sodium [149 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 158) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SALMONELLOSIS [DEATH - SALMONELLA EMPYEMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 652) the subject experienced salmonellosis [death - salmonella empyema] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 146 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the salmonellosis and up to 30 days prior to event onset included: fenofibrate, niacin extended-release (> 200 mg/day only), and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.23 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [32 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [17.14 mmol/L, range = (2.86 - 8.21)], high creatine kinase [247 IU/L, range = (20 - 203)], high creatinine [165 umol/L, range = (62 - 106)], high glucose [8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [123 IU/L, range = (20 - 203), BL =high], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 652) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): NEOPLASM MALIGNANT [CANCER COMPLICATIONS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 269) the subject experienced neuroendocrine carcinoma metastatic [neuroenodocrine carcinoma metatatis to liver and bone] (Grade 4) and on PPD (Day 312) the subject died due to neoplasm malignant [cancer complications] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 18 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the neoplasm malignant and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [128 g/L, range = (130 - 175)], and high potassium [5.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 80), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], normal hematocrit [0.42 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [136 g/L, range = (130 - 175), BL =low], normal platelets [323 10^9/L, range = (140 - 450), BL = missing], and normal potassium [4.9 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 312) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): AMYLOIDOSIS [AMYLOIDOSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Renal)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 351) the subject experienced amyloidosis (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 335 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the amyloidosis and up to 30 days prior to event onset included: acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [51 mL/min/1.73m2, range = (60 - 9999)], high creatine kinase [269 IU/L, range = (24 - 250)], low hematocrit [0.4 fraction of 1, range = (0.4 - 0.52)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 351) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 298) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 44 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.64 mg/L, range = (0 - 3)], and low thyrotropin [<0.01 mU/L]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** low glucose [4.4 mmol/L, range = (4.6 - 6.4), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 298) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CEREBRAL HAEMORRHAGE [CEREBRAL HEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 120) the subject experienced cerebral haemorrhage [cerebral hemorrhage] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 35 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebral haemorrhage and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high creatine kinase [230 IU/L, range = (20 - 203)], high glucose [10 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], and high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 120) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 747) the subject experienced death [death nos]. The event occurred 249 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.28 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high creatinine [91 umol/L, range = (44 - 80)], high glucose [6.4 mmol/L, range = (4.1 - 5.9)], high leukocytes [tntc /HPF, range = 0-12], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high protein [trace, range = NEGATIVE], and high urate [506 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 421), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14), BL =normal], normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], low hematocrit [0.35 fraction of 1, range = (0.35 - 0.47), BL =normal], low hemoglobin [113 g/L, range = (116 - 162), BL =normal], normal leukocytes [4-12 /HPF, range = 0-12, BL =high], normal magnesium [0.75 mmol/L, range = (0.65 - 1.05), BL =low], and normal urate [286 umol/L, range = (143 - 339), BL =high].

Action taken with IP and statin was not reported.The investigator's opinion of the relationship

between the event and IP and event and statin was not reported. The event ended on PPD (Day 747).

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CHRONIC OBSTRUCTIVE PULMONARY DISEASE [COPD]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 463) the subject experienced chronic obstructive pulmonary disease [copd] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 126 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the chronic obstructive pulmonary disease and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.52 mg/L, range = (0 - 3)], high glucose [8.4 mmol/L, range = (4.6 - 6.4)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 339), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [132 U/L, range = (40 - 129), BL =normal], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [118 umol/L, range = (62 - 106), BL =normal], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], high occult blood [2+, range = NEGATIVE, BL =normal], and low sodium [134 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 463) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 522) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 269 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: over the counter omega-3 fish oil, and pravastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high calcium [2.65 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55)], high glucose [7.2 mmol/L, range = (4.6 - 6.4)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 171), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.55 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.55 mmol/L, range = (2.2 - 2.55), BL =high], normal glucose [6.3 mmol/L, range = (4.6 - 6.4), BL =high], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 522) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [RESPIRATION FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1055) the subject experienced respiratory failure [respiration failure] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 46 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: omacor/lovaza, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.18 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high creatinine [110 umol/L, range = (62 - 106)], and low glucose [4.4 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.68 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.73 mmol/L, range = (2.2 - 2.55), BL =normal], low erythrocytes [3.5 10^12/L, range = (4 - 5.8), BL =normal], high glucose [7.2 mmol/L, range = (4.6 - 6.4), BL =low], low hemoglobin [117 g/L, range = (130 - 177), BL =normal], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06), BL =normal], low magnesium [0.57 mmol/L, range = (0.65 - 1.05), BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1055) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 446) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, apixaban, atorvastatin, beta blocker, clopidogrel, glycemic control medication, over the counter omega-3 fish oil, rocephin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high leukocytes [13-30 /HPF, range = 0-12], high alanine aminotransferase [35 U/L, range = (4 - 33)], high creatine kinase [414 IU/L, range = (24 - 160)], high creatinine [125 umol/L, range = (44 - 80)], high glucose [9.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [416 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 343), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [157 U/L, range = (35 - 104), BL =normal], high aspartate aminotransferase [50 U/L, range = (4 - 31), BL =normal], high calcium [2.6 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.7 mmol/L, range = (2.2 - 2.55), BL =normal], normal creatine kinase [76 IU/L, range = (24 - 160), BL =high], and normal urate [280 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 446) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 326) the subject experienced myocardial infarction. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 68 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [34 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], high creatinine [148 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], high glucose [7.4 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 174), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [8.21 mmol/L, range = (2.86 - 8.21), BL =high], normal erythrocytes [4.2 10^12/L, range = (4 - 5.8), BL =low], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], and high leukocytes [4-12 /HPF, range = 0-3, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 326) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 966) the subject experienced lung neoplasm malignant [worsening of lung cancer] (Grade 3) and on PPD (Day 969) the subject died. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 810 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ceftriaxone, cephalexin, keflex, rosuvastatin, vancomycin, zithromax, and zosyn.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.37 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.64 mmol/L, range = (2.86 - 8.21)], high creatinine [167 umol/L, range = (62 - 106)], high erythrocytes [6.1 10^12/L, range = (4 - 5.8)], high glucose [12.2 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high hematocrit [0.55 fraction of 1, range = (0.37 - 0.5)], high hemoglobin [183 g/L, range = (130 - 177)], high protein [1+, range = NEGATIVE], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 838), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [179 U/L, range = (40 - 129), BL =normal], high creatine kinase [309 IU/L, range = (20 - 203), BL =normal], low erythrocytes [3.6 10^12/L, range = (4 - 5.8), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], low hematocrit [0.31 fraction of 1, range = (0.37 - 0.5), BL =high], low hemoglobin [94 g/L, range = (130 - 177), BL =high], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06), BL =normal], high potassium [5.8 mmol/L, range = (3.3 - 5.1), BL =normal], and high protein [90 g/L, range = (60 -

80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 969) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ACUTE RESPIRATORY FAILURE [ACUTE RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 654) the subject experienced acute respiratory failure. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 568 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute respiratory failure and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high glucose [10.6 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], low hemoglobin [124 g/L, range = (130 - 177)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 100), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.9 10^12/L, range = (4 - 5.8), BL =normal], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5), BL =normal], and high leukocytes [13.4 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 654) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): INTRACRANIAL MASS [BRAIN MASS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 791) the subject experienced intracranial mass [brain mass] (Grade 3) and lung cancer metastatic (grade 4). On PPD (Day 818) the subject died due to intracranial mass [brain mass]. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 481 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline: normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 818) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SEPSIS [SEPTICEMIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 964) the subject experienced sepsis [septicemia] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 291 days after the last dose of any study medication.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high calcium [2.6 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55)], and high creatinine [85 umol/L, range = (44 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 847), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.5 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.55 mmol/L, range = (2.2 - 2.55), BL =high], low erythrocytes [3.5 10^12/L, range = (3.8 - 5.4), BL =normal], low glucose [4.3 mmol/L, range = (4.6 - 6.4), BL =normal], high glucose [trace, range = NEGATIVE, BL =normal], low hematocrit [0.31 fraction of 1, range = (0.33 - 0.46), BL =normal], low hemoglobin [96 g/L, range = (110 - 161), BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 964) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DYSPNOEA [SHORTNESS OF BREATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 385) the subject experienced dyspnoea [shortness of breath] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 48 days after the last dose of any study medication.

Concomitant medications taken at the onset of the dyspnoea and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.66 mg/L, range = (0 - 3)], low thyroxine [6.7 pmol/L, range = (11.5 - 22.7)], low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], low calcium [2 mmol/L, range = (2.2 - 2.55)], low calcium corrected [2.05 mmol/L, range = (2.2 - 2.55)], high creatinine [141 umol/L, range = (62 - 106)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], high glucose [7.1 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.34 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [109 g/L, range = (130 - 177)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], normal CRP [0.44 mg/L, range = (0 - 3), BL =high], normal calcium [2.23 mmol/L, range = (2.2 - 2.55), BL =low], normal calcium corrected [2.28 mmol/L, range = (2.2 - 2.55), BL =low], and high urate [422 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 385) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 168) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 82 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.32 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [43 mL/min/1.73m2, range = (60 - 9999)], high creatinine [118 umol/L, range = (62 - 106)], high erythrocytes [6-8 /HPF, range = 0-5], high glucose [8 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [trace, range = NEGATIVE], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14), BL =normal], and low protein [59 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 168) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 619) the subject experienced cerebrovascular accident [stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and over the counter omega-3 fish oil.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [56 mL/min/1.73m2, range = (60 - 9999)], and high urate [482 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 511), the subject had the following on-study laboratory test results with results different than baseline:** low glucose [3.9 mmol/L, range = (4.6 - 6.4), BL =normal], and high leukocytes [4-12 /HPF, range = 0-3, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 619) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): BASAL GANGLIA HAEMORRHAGE [LEFT BASAL GANGLIA HEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 370) the subject experienced basal ganglia haemorrhage [left basal ganglia hemorrhage] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the basal ganglia haemorrhage and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.29 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [109 umol/L, range = (44 - 80)], high erythrocytes [tntc /HPF, range = 0-8], high occult blood [3+, range = NEGATIVE], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], high protein [1+, range = NEGATIVE], and high urate [404 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 339), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [1.45 mg/L, range = (0 - 3), BL =high], normal occult blood [negative, range = NEGATIVE, BL =high], and normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 370) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 580) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 242 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, cefdinir, cleocin, clindamycin, fluconazole, levofloxacin, meropenam, metronidazole, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high alkaline phosphatase [118 U/L, range = (35 - 104)], high blood urea nitrogen [11.07 mmol/L, range = (2.86 - 8.21)], high creatinine [89 umol/L, range = (44 - 80)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high glucose [21.2 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high hematocrit [0.48 fraction of 1, range = (0.33 - 0.46)], high lactate dehydrogenase [269 U/L, range = (5 - 250)], high leukocytes [13-30 /HPF, range = 0-12], high protein [2+, range = NEGATIVE], high specific gravity [1.04, range = (1 - 1.04)], and high thyrotropin [7.17 mU/L, range = (0.55 - 4.78)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 338), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [33 g/L, range = (35 - 52), BL =normal], normal creatinine [80 umol/L, range = (44 - 80), BL =high], normal hematocrit [0.45 fraction of 1, range = (0.33 - 0.46), BL =high], high HbA1c [0.14 fraction of 1, range = (0.04 - 0.06), BL = missing], normal lactate dehydrogenase [244 U/L, range = (5 - 250), BL =high], normal leukocytes [4-12 /HPF, range = 0-12, BL =high], high platelets [452 10^9/L, range = (140 - 450), BL =normal], normal specific gravity [1.03, range = (1 - 1.04), BL =high], and high urate [393 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 580) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 370) the subject experienced death [unknown death] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 4 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: azithromycin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.34 mg/L, range = (0 - 3)], low bilirubin [2 umol/L, range = (3 - 21)], high glucose [5.9 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 358), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [7 umol/L, range = (3 - 21), BL =low], high creatine kinase [811 IU/L, range = (24 - 250), BL =normal], normal hematocrit [0.43 fraction of 1, range = (0.4 - 0.52), BL =low], and high urate [434 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and related to statin. The event ended on PPD (Day 370) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH UNASCERTAINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 404) the subject experienced death [death unascertained]. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline: low glucose [4.3 mmol/L, range = (4.6 - 6.4), BL =normal], and normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 404) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Renal)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 780) the subject experienced death. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 30 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and azithromycin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 666), the subject had the following on-study laboratory test results with results different than baseline: high glucose [7.3 mmol/L, range = (4.6 - 6.4), BL =normal], high protein [81 g/L, range = (60 - 80), BL =normal], and high urate [529 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 780) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 527) the subject experienced invasive ductal breast carcinoma [recurrent invasive ductal breast carcinoma] (Grade 4) and PPD (Day 666) the subject experienced death [death nos]. The event was considered serious for the following reasons: results in death. The event occurred 567 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: clopidogrel, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.8 mmol/L, range = (4.6 - 6.4)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 511), the subject had the following on-study laboratory test results with results different than baseline:** high CRP [3.52 mg/L, range = (0 - 3), BL =normal], high calcium [2.63 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55), BL =normal], high creatinine [83 umol/L, range = (44 - 80), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], normal glucose [6 mmol/L, range = (4.6 - 6.4), BL =high], and high urate [369 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 666) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE CONGESTIVE [CONGESTIVE HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 87) the subject experienced cardiac failure congestive [congestive heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 66 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure congestive and up to 30 days prior to event onset included: atorvastatin, colestipol, and over the counter omega-3 fish oil.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.87 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [22 umol/L, range = (3 - 21)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], high creatinine [116 umol/L, range = (62 - 106)], high glucose [12.1 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.4 fraction of 1, range = (0.4 - 0.52)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 87) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 516) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 25 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, fenofibrate, glycemic control medication, insulin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.16 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [38 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.64 mmol/L, range = (2.14 - 7.14)], high creatinine [154 umol/L, range = (62 - 106)], high glucose [6 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high protein [2+, range = NEGATIVE], and high urate [541 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.9 10^12/L, range = (4.1 - 5.9), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [trace, range = NEGATIVE, BL =normal], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52), BL =normal], and low hemoglobin [123 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 516) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 788) the subject experienced adenocarcinoma gastric [adenocarcinoma of gastrojejunal anastomosis] (Grade 3) and on PPD (Day 806) the subject died due to the event. The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 49 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high leukocytes [tntc /HPF, range = 0-3], and high occult blood [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [147 U/L, range = (40 - 129), BL =normal], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], high lactate dehydrogenase [270 U/L, range = (5 - 250), BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 806) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 139) the subject experienced gastric cancer stage iv [stage 4 gastric carcinoma] (Grade 4) and on PPD (Day 269) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 268 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.81 mg/L, range = (0 - 3)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 269) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 544) the subject experienced death (Grade 4). The event was considered serious for the following reasons: requires or prolongs hospitalization. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, bactrim, and cephalexin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.07 mmol/L, range = (2.86 - 8.21)], high calcium [2.7 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.78 mmol/L, range = (2.2 - 2.55)], high creatinine [144 umol/L, range = (62 - 106)], high glucose [11.5 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], low hemoglobin [125 g/L, range = (130 - 177)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], low platelets [93 10^9/L, range = (140 - 450)], high protein [3+, range = NEGATIVE], low protein [59 g/L, range = (60 - 80)], and high urate [571 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [4.9 mmol/L, range = (4.6 - 6.4), BL =high], normal glucose [negative, range = NEGATIVE, BL =high], normal hemoglobin [153 g/L, range = (130 - 177), BL =low], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 544) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 850) the subject experienced death [unknown cause of death]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, augmentin, bactrim ds, beta blocker, ciprofloxacin, gentamicin, and trimethoprim/sulfa ds 160/800.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.07 mg/L, range = (0 - 3)], high thyrotropin [5.33 mU/L, range = (0.55 - 4.78)], high erythrocytes [15-30 /HPF, range = 0-5], high leukocytes [tntc /HPF, range = 0-3], high occult blood [1+, range = NEGATIVE], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 841), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [213 IU/L, range = (20 - 203), BL =normal], high creatinine [111 umol/L, range = (62 - 106), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], high glucose [7.7 mmol/L, range = (4.6 - 6.4), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 850) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PNEUMONIA [PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 438) the subject experienced pneumonia (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 17 days after the last dose of any study medication.

Concomitant medications taken at the onset of the pneumonia and up to 30 days prior to event onset included: acetylsalicylic acid, antidepressants, atorvastatin, azithromycin, beta blocker, cefazolin, cefepime, cephalexin, minocycline, oral corticosteroids, pipercilling-tazobactam, rifampin, vancomycin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [33.13 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [40 mL/min/1.73m2, range = (60 - 9999)], high creatinine [114 umol/L, range = (44 - 80)], low sodium [134 mmol/L, range = (135 - 147)], and high urate [434 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 346), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.63 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55), BL =normal], normal sodium [141 mmol/L, range = (135 - 147), BL =low], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 438) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ROAD TRAFFIC ACCIDENT [PPD]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 353) the subject experienced road traffic accident [PPD] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 282 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the road traffic accident and up to 30 days prior to event onset included: atorvastatin, beta blocker, clopidogrel, and vitamin supplements.

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 353) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 65) the subject was reported with myocardial infarction [myocardial infarct] (Grade 4) and on PPD (Day 65) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [214 IU/L, range = (20 - 203)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 65) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): INTRACRANIAL ANEURYSM [CEREBRAL ARTERIAL ANEURYSM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 571) the subject experienced intracranial aneurysm [cerebral arterial aneurysm] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 66 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the intracranial aneurysm and up to 30 days prior to event onset included: simvastatin.

The subject had the following abnormal laboratory test results at baseline: low leukocytes [2.7 10^9/L, range = (4.1 - 12.3)], low platelets [118 10^9/L, range = (140 - 450)], high calcium [2.6 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.6 mmol/L, range = (2.2 - 2.55)], high creatinine [93 umol/L, range = (44 - 80)], high glucose [6.6 mmol/L, range = (4.6 - 6.4)], high leukocytes [tntc /HPF, range = 0-12], and high urate [404 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.3 mmol/L, range = (4.6 - 6.4), BL =high], normal leukocytes [4-12 /HPF, range = 0-12, BL =high], and normal platelets [151 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 571) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 577) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 71 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [40 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.14 mmol/L, range = (2.86 - 8.21)], high creatinine [153 umol/L, range = (62 - 106)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high potassium [5.5 mmol/L, range = (3.3 - 5.1)], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 506), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [212 IU/L, range = (20 - 203), BL =normal], high direct bilirubin [6 umol/L, range = (0 - 5), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high glucose [8.7 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [122 g/L, range = (130 - 177), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], normal potassium [4.4 mmol/L, range = (3.3 - 5.1), BL =high], high protein [trace, range = NEGATIVE, BL =normal], and low protein [57 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 577) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 818) the subject experienced cardiac failure congestive [congestive heart failure] (Grade 3) and on PPD (Day 827) the subject died. The event was considered serious for the following reasons: requires or prolongs hospitalization, and is life threatening. The event occurred 41 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, ceftin, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.13 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [27 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.85 mmol/L, range = (2.86 - 8.21)], high creatinine [194 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], high erythrocytes [6-8 /HPF, range = 0-5], high glucose [11.2 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [114 g/L, range = (130 - 177)], high occult blood [trace, range = NEGATIVE], high protein [2+, range = NEGATIVE], and high urate [488 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 679), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], normal glucose [negative, range = NEGATIVE, BL =high], low platelets [131 10^9/L, range = (140 - 450), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 827) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 16) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 15 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, beta blocker, fenofibrate, glycemic control medication, insulin, other prescription omega-3 fish oil, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [10 mmol/L, range = (2.86 - 8.21)], high calcium [2.63 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.63 mmol/L, range = (2.2 - 2.55)], high creatine kinase [204 IU/L, range = (20 - 203)], high creatinine [118 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], high glucose [10 mmol/L, range = (4.6 - 6.4)], high glucose [1+, range = NEGATIVE], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [119 g/L, range = (130 - 177)], low leukocytes [3.8 10^9/L, range = (4.1 - 12.3)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 16) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): METABOLIC ENCEPHALOPATHY [METABOLIC ENCEPHALOPATHY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Other Non-Cardiovascular) (Failure To Thrive)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On P P the subject was hospitalized with abdominal pain, nausea, vomiting, dysphagia, dehydration, weight loss, and confusion, and was diagnosed with metabolic encephalopathy. Head CT showed no acute process. EEG was consistent with metabolic encephalopathy. On PPD (Day 348) the subject died due to metabolic encephalopathy. The event occurred 88 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [47 mL/min/1.73m2, range = (60 - 9999)], high creatinine [108 umol/L, range = (62 - 106)], high glucose [10.5 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** low platelets [135 10^9/L, range = (140 - 450), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 348) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN CARDIAC DEATH [SUDDEN CARDIAC DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 378) the subject experienced sudden cardiac death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 43 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden cardiac death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high calcium [2.63 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58)], high creatinine [111 umol/L, range = (62 - 106)], high glucose [6.4 mmol/L, range = (4.1 - 5.9)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], high protein [1+, range = NEGATIVE], and high urate [500 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 335), the subject had the following on-study laboratory test results with results different than baseline:** normal calcium [2.48 mmol/L, range = (2.1 - 2.58), BL =high], normal calcium corrected [2.48 mmol/L, range = (2.1 - 2.58), BL =high], normal glucose [5.7 mmol/L, range = (4.6 - 6.4), BL =high], low platelets [123 10^9/L, range = (140 - 450), BL =normal], and normal potassium [5 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 378) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIOPULMONARY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 275) the subject experienced cardio-respiratory arrest [cardiopulmonary arrest] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 23 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.83 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [35 mL/min/1.73m2, range = (60 - 9999)], low albumin [33 g/L, range = (35 - 52)], high alkaline phosphatase [260 U/L, range = (40 - 129)], high bilirubin [31 umol/L, range = (3 - 21)], high blood urea nitrogen [10.35 mmol/L, range = (2.14 - 7.14)], high creatinine [208 umol/L, range = (62 - 106)], high direct bilirubin [14 umol/L, range = (0 - 5)], high glucose [9.4 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [57 U/L, range = (4 - 41), BL =normal], normal albumin [41 g/L, range = (35 - 52), BL =low], low erythrocytes [4 10^12/L, range = (4.1 - 5.9), BL =normal], low hematocrit [0.38 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [125 g/L, range = (130 - 175), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and high urate [541 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 275) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): ARRHYTHMIA [CARDIAC ARRHYTHMIA NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 440) the subject experienced arrhythmia [cardiac arrhythmia nos] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 439 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the arrhythmia and up to 30 days prior to event onset included: acetylsalicylic acid, clopidogrel, fenofibrate, over the counter omega-3 fish oil, rosuvastatin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [17.4 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high creatinine [113 umol/L, range = (62 - 106)], low erythrocytes [4 10^12/L, range = (4.1 - 5.9)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [127 g/L, range = (130 - 175)], low leukocytes [4 10^9/L, range = (4.1 - 12.3)], and low magnesium [0.6 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 339), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [43 U/L, range = (4 - 37), BL =normal], high creatine kinase [361 IU/L, range = (24 - 250), BL =normal], normal erythrocytes [4.2 10^12/L, range = (4.1 - 5.9), BL =low], normal hematocrit [0.4 fraction of 1, range = (0.4 - 0.52), BL =low], normal hemoglobin [131 g/L, range = (130 - 175), BL =low], normal leukocytes [6.4 10^9/L, range = (4.1 - 12.3), BL =low], high protein [trace, range = NEGATIVE, BL =normal], and high urate [589 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 440) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH FROM NATURAL CAUSES]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 128) the subject experienced death [death from natural causes] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 45 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [36 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.42 mmol/L, range = (2.14 - 7.14)], high creatinine [144 umol/L, range = (44 - 80)], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.5)], high glucose [7.5 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.31 fraction of 1, range = (0.35 - 0.47)], low hemoglobin [101 g/L, range = (116 - 162)], high leukocytes [13-30 /HPF, range = 0-12], and high urate [732 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 83), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [3.8 10^12/L, range = (3.8 - 5.5), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 128) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 37) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 8 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, clopidogrel, fenofibrate, glycemic control medication, niacin extended-release (> 200 mg/day only), over the counter omega-3 fish oil, vitamin supplements, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high creatinine [133 umol/L, range = (62 - 106)], high glucose [7.8 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 37) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 156) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 1 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high glucose [6.5 mmol/L, range = (4.1 - 5.9)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 156) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 969) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 43 days after the last dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, cefdinir, and omnicef.

The subject had the following abnormal laboratory test results at baseline: high glucose [12.9 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [126 g/L, range = (130 - 175)], high leukocytes [4-12 /HPF, range = 0-3], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 846), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [135 umol/L, range = (62 - 106), BL =normal], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and high urate [529 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 969) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [DEATH SUDDEN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 531) the subject experienced sudden death [death sudden] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 23 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, atorvastatin, beta blocker, clopidogrel, glycemic control medication, and insulin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.21 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatine kinase [224 IU/L, range = (20 - 203)], high creatinine [118 umol/L, range = (62 - 106)], high glucose [9 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [3+, range = NEGATIVE], and high urate [684 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 508), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [134 IU/L, range = (20 - 203), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 531) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Hepatobiliary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1108) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 68 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high alanine aminotransferase [50 U/L, range = (4 - 41)], high aspartate aminotransferase [52 U/L, range = (4 - 37)], low creatinine [59 umol/L, range = (62 - 106)], and high potassium [5.2 mmol/L, range = (3.3 - 5.1)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [176 U/L, range = (40 - 129), BL =normal], high bilirubin [22 umol/L, range = (3 - 21), BL =normal], high direct bilirubin [9 umol/L, range = (0 - 5), BL =normal], high lactate dehydrogenase [269 U/L, range = (5 - 250), BL =normal], normal potassium [3.5 mmol/L, range = (3.3 - 5.1), BL =high], and high urate [440 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1108) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 362) the subject experienced death [unknown cause of death]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: co q-10, over the counter omega-3 fish oil, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.64 mg/L, range = (0 - 3)], high creatine kinase [224 IU/L, range = (20 - 203)], and low platelets [127 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 332), the subject had the following on-study laboratory test results with results different than baseline:** normal CRP [1.7 mg/L, range = (0 - 3), BL =high], normal creatine kinase [160 IU/L, range = (20 - 203), BL =high], and normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 362) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 327) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 64 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, doxycycline, vancomycin, and zosyn.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high creatinine [98 umol/L, range = (44 - 80)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high leukocytes [13-30 /HPF, range = 0-12], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high urate [351 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 177), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high], normal leukocytes [0-3 /HPF, range = 0-12, BL =high], and normal potassium [4.4 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 327) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 553) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 55 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.79 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [48 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high creatine kinase [260 IU/L, range = (20 - 203)], high creatinine [133 umol/L, range = (62 - 106)], high glucose [7 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], and high urate [506 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline:** high glucose [2+, range = NEGATIVE, BL =normal], and high protein [2+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 553) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIOPULMONARY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 534) the subject experienced cardio-respiratory arrest [cardiopulmonary arrest]. The event was considered serious for the following reasons: results in death. The event occurred 197 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [11.39 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high leukocytes [31-50 /HPF, range = 0-12], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high creatinine [80 umol/L, range = (44 - 80), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 534) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 875) the subject experienced death. The event was considered serious for the following reasons: results in death, is life threatening, and other medically important serious event. The event occurred 846 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [10.02 mg/L, range = (0 - 3)], high aspartate aminotransferase [88 U/L, range = (4 - 37)], high hepatitis C virus antibody [positive, range = NEGATIVE], high hepatitis C virus antibody [positive, range = NEGATIVE], high alanine aminotransferase [42 U/L, range = (4 - 41)], high glucose [8.2 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low platelets [132 10^9/L, range = (140 - 450)], and high protein [81 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 875) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 853) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 96 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and fenofibrate.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [30 mL/min/1.73m2, range = (60 - 9999)], high creatinine [179 umol/L, range = (62 - 106)], high glucose [7.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 681), the subject had the following on-study laboratory test results with results different than baseline:** low erythrocytes [3.6 10^12/L, range = (4 - 5.8), BL =normal], high glucose [trace, range = NEGATIVE, BL =normal], low hematocrit [0.33 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [106 g/L, range = (130 - 177), BL =normal], and normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 853) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): VENTRICULAR FIBRILLATION [RECURRENT VENTRICULAR FIBRILLATION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 572) the subject experienced ventricular fibrillation [recurrent ventricular fibrillation] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the ventricular fibrillation and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high creatinine [109 umol/L, range = (62 - 106)], low glucose [3.2 mmol/L, range = (4.6 - 6.4)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal creatinine [92 umol/L, range = (62 - 106), BL =high], low erythrocytes [3.9 10^12/L, range = (4 - 5.8), BL =normal], normal glucose [5.6 mmol/L, range = (4.6 - 6.4), BL =low], low hemoglobin [119 g/L, range = (130 - 177), BL =normal], high protein [1+, range = NEGATIVE, BL =normal], and low protein [57 g/L, range = (60 - 80), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 572) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBRAL HAEMORRHAGE [HEMORRHAGE BRAIN]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 635) the subject experienced cerebral haemorrhage [hemorrhage brain] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 46 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebral haemorrhage and up to 30 days prior to event onset included: atorvastatin, azithromycin, rocephin, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.66 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [7.5 mmol/L, range = (2.14 - 7.14)], high creatinine [118 umol/L, range = (62 - 106)], high erythrocytes [9-14 /HPF, range = 0-5], high glucose [7.8 mmol/L, range = (4.1 - 5.9)], high glucose [2+, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], high occult blood [1+, range = NEGATIVE], and high protein [3+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** low bilirubin [2 umol/L, range = (3 - 21), BL =normal], high creatine kinase [599 IU/L, range = (24 - 250), BL =normal], low erythrocytes [3.6 10^12/L, range = (4.1 - 5.9), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL =high], low hematocrit [0.3 fraction of 1, range = (0.4 - 0.52), BL =normal], low hemoglobin [97 g/L, range = (130 - 175), BL =normal], high lactate dehydrogenase [252 U/L, range = (5 - 250), BL =normal], normal protein [4+, range = NEGATIVE, BL =high], and high sodium [149 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 635) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): BREAST CANCER [BREAST CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 583) the subject experienced breast cancer (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 50 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the breast cancer and up to 30 days prior to event onset included: (augmentin) amoxicillin 875mg/ pot clavulanate 125mg, (augmentin) amoxicillin-pot clavulanate, 1- 1gm rocephin injection, 1- 1gm rochephin injection, 1- 40mg kenalog injection, 1- 60mg kenalog injection, amoxicillin-pot clavulanate (augmentin), atorvastatin, ceftriaxone (rocephin), cefuroxime axetil (ceftin), cephalexin (keflex), ciprofloxacin, clindamycin hcl, flagyl, nystatin, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high CRP [24.8 mg/L, range = (0 - 3)], high creatinine [98 umol/L, range = (44 - 80)], low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high leukocytes [16.8 10^9/L, range = (4.1 - 12.3)], and high urate [410 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [151 U/L, range = (35 - 104), BL =normal], and normal urate [327 umol/L, range = (143 - 339), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 583) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DISEASE PROGRESSION [DISEASE PROGRESSION NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 575) the subject experienced disease progression [disease progression nos] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 406 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the disease progression and up to 30 days prior to event onset included: azithromycin, ceftin 500mg, kenalog injection, levofloxacin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.8 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [9.28 mmol/L, range = (2.14 - 7.14)], high calcium [2.78 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.78 mmol/L, range = (2.1 - 2.58)], high creatinine [121 umol/L, range = (44 - 80)], high glucose [6.4 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high leukocytes [14.7 10^9/L, range = (4.1 - 12.3)], high protein [trace, range = NEGATIVE], and high urate [416 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], and high lactate dehydrogenase [259 U/L, range = (5 - 250), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 575) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): OVARIAN CANCER [OVARIAN CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 427) the subject experienced ovarian cancer (Grade 4). The event was considered serious for the following reasons: results in death, and other medically important serious event. The event occurred 254 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the ovarian cancer and up to 30 days prior to event onset included: amoxicillin- pot clavulanate, atorvastatin, cefazolin, levaquin, and minocycline.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.14 mU/L, range = (0.55 - 4.78)], high thyroxine [25.5 pmol/L, range = (11.5 - 22.7)], high alkaline phosphatase [115 U/L, range = (35 - 104)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [133 umol/L, range = (44 - 80)], high protein [2+, range = NEGATIVE], and high urate [476 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 173), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], normal blood urea nitrogen [7.5 mmol/L, range = (2.86 - 8.21), BL =high], and high leukocytes [13-30 /HPF, range = 0-12, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 427) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE CONGESTIVE [CONGESTIVE HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 727) the subject experienced cardiac failure congestive [congestive heart failure] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, and is life threatening. The event occurred 131 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure congestive and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [38 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [24 umol/L, range = (3 - 21)], high blood urea nitrogen [8.57 mmol/L, range = (2.14 - 7.14)], high creatinine [149 umol/L, range = (62 - 106)], high direct bilirubin [7 umol/L, range = (0 - 5)], high glucose [20.8 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 519), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [19 umol/L, range = (3 - 21), BL =high], high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal], low sodium [130 mmol/L, range = (135 - 147), BL =normal], and high urate [434 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 727) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [HYPOXIC RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 585) the subject experienced respiratory failure [hypoxic respiratory failure] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 10 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: ezetimibe, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.84 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [14.28 mmol/L, range = (2.86 - 8.21)], high calcium [2.65 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55)], high creatinine [119 umol/L, range = (62 - 106)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], high protein [2+, range = NEGATIVE], and high urate [506 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 512), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.43 mmol/L, range = (2.86 - 8.21), BL =high], high erythrocytes [15-30 /HPF, range = 0-5, BL =normal], low glucose [4.4 mmol/L, range = (4.6 - 6.4), BL =normal], high leukocytes [13-30 /HPF, range = 0-3, BL =normal], high occult blood [2+, range = NEGATIVE, BL =normal], and normal potassium [4.5 mmol/L, range = (3.3 - 5.1), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 585) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 81) the subject experienced death [death nos]. The event was considered serious for the following reasons: results in death. The event occurred 33 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [37.38 mg/L, range = (0 - 3)], low creatinine [58 umol/L, range = (62 - 106)], high leukocytes [13.4 10^9/L, range = (4.1 - 12.3)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 81) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 181) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 89 days after the last dose of any study medication.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.38 mg/L, range = (0 - 3)], and high alkaline phosphatase [136 U/L, range = (40 - 129)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 92), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [127 U/L, range = (40 - 129), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 181) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PNEUMONIA LEGIONELLA [LEGIONELLA PNEUMOPHILA PNEUMONIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 604) the subject experienced pneumonia legionella [legionella pneumophila pneumonia] (Grade 4) and on PPD (Day 608) the subject died due to the event. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 15 days after the last dose of any study medication.

Concomitant medications taken at the onset of the pneumonia legionella and up to 30 days prior to event onset included: acetylsalicylic acid, angiotensin receptor blocker, atorvastatin, beta blocker, neomycin, prasugrel, simvastatin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], low platelets [129 10^9/L, range = (140 - 450)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 509), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.03 mmol/L, range = (2.86 - 8.21), BL =high], and normal platelets [149 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 608) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 130) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 45 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.19 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [145 U/L, range = (35 - 104)], high creatine kinase [345 IU/L, range = (24 - 170)], high creatinine [99 umol/L, range = (44 - 80)], high glucose [19.8 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 117), the subject had the following on-study laboratory test results with results different than baseline:** normal glucose [5.8 mmol/L, range = (4.1 - 5.9), BL =high], low potassium [3.2 mmol/L, range = (3.3 - 5.1), BL =normal], and high urate [642 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 130) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 778) the subject experienced death [death nos] (Grade 3). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, aldosterone antagonist, analgesic or antipyretic agent, atorvastatin, beta blocker, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [264 IU/L, range = (24 - 170)], high creatinine [88 umol/L, range = (44 - 80)], high lactate dehydrogenase [355 U/L, range = (5 - 250)], high protein [trace, range = NEGATIVE], and high urate [452 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [107 U/L, range = (35 - 104), BL =normal], normal choriogonadotropin beta [negative, range = NEGATIVE, BL = missing], and normal creatinine [73 umol/L, range = (44 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 778) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 159) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 74 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.49 mg/L, range = (0 - 3)], high bilirubin [1+, range = NEGATIVE], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], high hematocrit [0.53 fraction of 1, range = (0.4 - 0.52)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** low blood urea nitrogen [2.5 mmol/L, range = (2.86 - 8.21), BL =normal], normal glucose [6.3 mmol/L, range = (4.6 - 6.4), BL =high], and high leukocytes [14.2 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 159) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 792) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 764 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: cefepime, ceftriaxone, meropenem, rosuvastatin, vancomycin, and zosyn.

The subject had the following abnormal laboratory test results at baseline: high CRP [32.21 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [138 U/L, range = (35 - 104)], high blood urea nitrogen [14.64 mmol/L, range = (2.14 - 7.14)], high calcium [2.6 mmol/L, range = (2.1 - 2.58)], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58)], high creatinine [152 umol/L, range = (44 - 80)], low glucose [<2.2 mmol/L], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high leukocytes [13.7 10^9/L, range = (4.1 - 12.3)], high leukocytes [tntc /HPF, range = 0-12], high occult blood [trace, range = NEGATIVE], and high urate [613 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 792) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH UNEXPLAINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 570) the subject experienced death [death unexplained] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 235 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, augmentin, azithromycin, ceftriaxone, levaquin, moxifloxacin (avelox), septra ds, and zyvox.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.31 mg/L, range = (0 - 3)], high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14)], low erythrocytes [3.6 10^12/L, range = (4.1 - 5.9)], low glucose [4 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], low hematocrit [0.33 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [111 g/L, range = (130 - 175)], high occult blood [trace, range = NEGATIVE], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 335), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [43 U/L, range = (4 - 41), BL =normal], high aspartate aminotransferase [53 U/L, range = (4 - 37), BL =normal], high calcium [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.73 mmol/L, range = (2.1 - 2.58), BL =normal], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], normal glucose [5.3 mmol/L, range = (4.1 - 5.9), BL =low], and high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 570) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 329) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 68 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, bactrim ds, invanz, over the counter omega-3 fish oil, and penicillin.

The subject had the following abnormal laboratory test results at baseline: high CRP [34.16 mg/L, range = (0 - 3)], high creatinine [108 umol/L, range = (62 - 106)], high glucose [23.7 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high protein [1+, range = NEGATIVE], and high urate [476 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [169 U/L, range = (40 - 129), BL =normal], normal creatinine [106 umol/L, range = (62 - 106), BL =high], normal protein [negative, range = NEGATIVE, BL =high], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 329) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH - UNDETERMINED]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 569) the subject experienced death [death - undetermined] (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 64 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, avelox, doxycycline, levaquin, levofloxacin, linezolid, and moxifloxacin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.84 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [31 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [105 U/L, range = (35 - 104)], high bilirubin [1+, range = NEGATIVE], high creatinine [149 umol/L, range = (44 - 80)], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.4)], high protein [1+, range = NEGATIVE], and high urate [529 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [88 U/L, range = (35 - 104), BL =high], high glucose [7.2 mmol/L, range = (4.6 - 6.4), BL =normal], and high leukocytes [tntc /HPF, range = 0-12, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 569) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 898) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, glycemic control medication, insulin, levaquin, oral corticosteroids, vancomycin, vitamin supplements, and warfarin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.27 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [47 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.42 mmol/L, range = (2.86 - 8.21)], low calcium [2.18 mmol/L, range = (2.2 - 2.55)], high creatinine [212 umol/L, range = (62 - 106)], high glucose [10.2 mmol/L, range = (4.6 - 6.4)], high lactate dehydrogenase [262 U/L, range = (5 - 250)], high leukocytes [4-12 /HPF, range = 0-3], high protein [2+, range = NEGATIVE], and high urate [738 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 872), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [99 U/L, range = (4 - 41), BL =normal], high alkaline phosphatase [180 U/L, range = (40 - 129), BL =normal], high aspartate aminotransferase [40 U/L, range = (4 - 37), BL =normal], high bilirubin [24 umol/L, range = (3 - 21), BL =normal], normal calcium [2.28 mmol/L, range = (2.2 - 2.55), BL =low], high direct bilirubin [12 umol/L, range = (0 - 5), BL =normal], high erythrocytes [5.9 10^12/L, range = (4 - 5.8), BL =normal], high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5), BL =normal], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06), BL =normal], and high leukocytes [16.7 10^9/L, range = (4.1 - 12.3), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 898) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 585) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 500 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high aspartate aminotransferase [36 U/L, range = (4 - 31)], low glucose [4.4 mmol/L, range = (4.6 - 6.4)], low hematocrit [0.34 fraction of 1, range = (0.35 - 0.47)], and low hemoglobin [109 g/L, range = (116 - 162)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 85), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [28 U/L, range = (4 - 31), BL =high], high creatine kinase [233 IU/L, range = (24 - 170), BL =normal], normal glucose [4.6 mmol/L, range = (4.6 - 6.4), BL =low], normal hematocrit [0.36 fraction of 1, range = (0.35 - 0.47), BL =low], and normal hemoglobin [120 g/L, range = (116 - 162), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 585) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 230) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 145 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: augmentin, fenofibrate, keflex, simvastatin, and zosyn.

The subject had the following abnormal laboratory test results at baseline: high CRP [20.72 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [33 mL/min/1.73m2, range = (60 - 9999)], high thyrotropin [4.88 mU/L, range = (0.55 - 4.78)], high blood urea nitrogen [15.35 mmol/L, range = (2.14 - 7.14)], high creatinine [184 umol/L, range = (62 - 106)], high glucose [20.8 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.12 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 230) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 462) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 45 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.35 mg/L, range = (0 - 3)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 330), the subject had the following on-study laboratory test results with results different than baseline:** normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL = missing], normal platelets [206 10^9/L, range = (140 - 450), BL = missing], and low urate [190 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 462) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): MYOCARDIAL INFARCTION [MYOCARDIAL INFARCTION]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 336) the subject experienced myocardial infarction (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 335 days after the first dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the myocardial infarction and up to 30 days prior to event onset included: ACE inhibitor, apixaban, beta blocker, fenofibrate, rosuvastatin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [45 mL/min/1.73m2, range = (60 - 9999)], high creatinine [147 umol/L, range = (62 - 106)], high glucose [6.9 mmol/L, range = (4.6 - 6.4)], high hematocrit [0.52 fraction of 1, range = (0.37 - 0.5)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], low platelets [120 10^9/L, range = (140 - 450)], high protein [trace, range = NEGATIVE], and high urate [512 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 336), the subject had the following on-study laboratory test results with results different than baseline:** low alkaline phosphatase [35 U/L, range = (40 - 129), BL =normal], normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high], normal HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =high], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], and normal platelets [166 10^9/L, range = (140 - 450), BL =low].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 336) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 845) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: analgesic or antipyretic agent, atorvastatin, bactroban, beta blocker, cephalexin, cipro, ciprofloxacin, clopidogrel, doxycycline, enoxaparin, fluzone high dose influenza vaccine, glycemic control medication, keflex, minocycline, pneumococcal vaccine, rocephin, septra ds, silvadene, tdap vaccine, triple antibiotic ointment, and vancomycin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.49 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], high aspartate aminotransferase [56 U/L, range = (4 - 31)], high blood urea nitrogen [12.85 mmol/L, range = (2.86 - 8.21)], high calcium [2.65 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.65 mmol/L, range = (2.2 - 2.55)], high creatinine [128 umol/L, range = (44 - 80)], high glucose [6.8 mmol/L, range = (4.6 - 6.4)], high leukocytes [31-50 /HPF, range = 0-12], and high urate [613 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 836), the subject had the following on-study laboratory test results with results different than baseline:** normal aspartate aminotransferase [13 U/L, range = (4 - 31), BL =high], normal calcium [2.35 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.38 mmol/L, range = (2.2 - 2.55), BL =high], high direct bilirubin [8 umol/L, range = (0 - 5), BL =normal], and low hemoglobin [109 g/L, range = (110 - 161), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 845) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): NECROTISING FASCIITIS [FOURNIER GANGRENE OF GENTALIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 162) the subject experienced necrotising fasciitis [fournier gangrene of gentalia] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 43 days after the last dose of any study medication.

Concomitant medications taken at the onset of the necrotising fasciitis and up to 30 days prior to event onset included: rosuvastatin, and zithromycon.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.33 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [115 umol/L, range = (62 - 106)], low platelets [132 10^9/L, range = (140 - 450)], high protein [trace, range = NEGATIVE], high sodium [148 mmol/L, range = (135 - 147)], and high urate [607 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 86), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.14 mmol/L, range = (2.86 - 8.21), BL =high], high glucose [9.9 mmol/L, range = (4.6 - 6.4), BL =normal], normal platelets [143 10^9/L, range = (140 - 450), BL =low], and normal sodium [147 mmol/L, range = (135 - 147), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 162) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): FEMORAL ARTERY ANEURYSM [FEMORAL ARTERY ANEURYSM]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Cardiovascular Hemorrhage)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 270) the subject experienced femoral artery aneurysm (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 3 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the femoral artery aneurysm and up to 30 days prior to event onset included: acetylsalicylic acid, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, clopidogrel, glycemic control medication, insulin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.48 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [11.78 mmol/L, range = (2.14 - 7.14)], high creatinine [133 umol/L, range = (62 - 106)], low glucose [4 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], and high urate [666 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [46 U/L, range = (4 - 41), BL =normal], high glucose [10.2 mmol/L, range = (4.1 - 5.9), BL =low], normal leukocytes [0-3 /HPF, range = 0-3, BL = missing], high occult blood [trace, range = NEGATIVE, BL =normal], and high protein [3+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 270) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): ACUTE CORONARY SYNDROME [NON ST SEGMENT ELEVATION ACUTE CORONARY SYNDROME]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To An Acute MI)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 713) the subject experienced acute coronary syndrome [non st segment elevation acute coronary syndrome]. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 446 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the acute coronary syndrome and up to 30 days prior to event onset included: atorvastatin, ezetimibe, keflax 500mg, meropenem, niacin short-acting (> 200 mg/day only), and over the counter omega-3 fish oil.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [37 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatinine [128 umol/L, range = (44 - 80)], high leukocytes [31-50 /HPF, range = 0-12], and high urate [500 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.6 mmol/L, range = (2.1 - 2.58), BL =normal], high lactate dehydrogenase [294 U/L, range = (5 - 250), BL =normal], and normal leukocytes [4-12 /HPF, range = 0-12, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 713) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 842) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 86 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and pravastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.68 mg/L, range = (0 - 3)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 672), the subject had the following on-study laboratory test results with results different than baseline:** normal leukocytes [0-3 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 842) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SEPTIC SHOCK [SEPTIC SHOCK]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 101) the subject experienced septic shock (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 12 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the septic shock and up to 30 days prior to event onset included: amoxi/k-clav, angiotensin receptor blocker, antidepressants, atorvastatin, azithromycin, beta blocker, clopidogrel, glycemic control medication, insulin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.78 mg/L, range = (0 - 3)], high alkaline phosphatase [116 U/L, range = (35 - 104)], low glucose [3.6 mmol/L, range = (4.6 - 6.4)], high glucose [3+, range = NEGATIVE], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 89), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [31 g/L, range = (35 - 52), BL =normal], and low calcium [2.05 mmol/L, range = (2.1 - 2.58), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 101) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC DISORDER [CARDIAC RELATED EVENT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 181) the subject experienced cardiac disorder [cardiac related event]. The event was considered serious for the following reasons: results in death. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac disorder and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, antidepressants, atorvastatin, beta blocker, fenofibrate, glycemic control medication, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [306 IU/L, range = (24 - 250)], high creatinine [149 umol/L, range = (62 - 106)], and low glomerular filtration rate, estimated [42 mL/min/1.73m2, range = (60 - 9999)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** normal creatine kinase [145 IU/L, range = (24 - 250), BL =high], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], and low hemoglobin [128 g/L, range = (130 - 175), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 181) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 1112) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, antidepressants, atorvastatin, bactrim ds, beta blocker, ciprofloxacin 500 mg, ciprofloxacn, ciprofloxacxin 500 mg, cleocin, clindamycin 300 mg, glycemic control medication, insulin, keflex 500 mg, minocycline, 100 mg, prasugrel, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [47 mL/min/1.73m2, range = (60 - 9999)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], high creatinine [114 umol/L, range = (62 - 106)], high glucose [16.7 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], and high protein [2+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [130 U/L, range = (40 - 129), BL =normal], high blood urea nitrogen [9.96 mmol/L, range = (2.14 - 7.14), BL =normal], low hemoglobin [107 g/L, range = (130 - 175), BL =normal], and high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 1112) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RENAL FAILURE [RENAL FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 798) the subject experienced renal failure (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 161 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the renal failure and up to 30 days prior to event onset included: acetylsalicylic acid, atorvastatin, beta blocker, over the counter omega-3 fish oil, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.99 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [41 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [126 umol/L, range = (62 - 106)], low erythrocytes [3.9 10^12/L, range = (4 - 5.8)], low hemoglobin [127 g/L, range = (130 - 177)], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 679), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [156 U/L, range = (40 - 129), BL =normal], normal erythrocytes [4 10^12/L, range = (4 - 5.8), BL =low], high erythrocytes [6-8 /HPF, range = 0-5, BL =normal], and high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 798) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PANCREATIC CARCINOMA METASTATIC [PANCREATIC CANCER METASTATIC]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 440) the subject experienced pancreatic carcinoma metastatic [pancreatic cancer metastatic] (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 103 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pancreatic carcinoma metastatic and up to 30 days prior to event onset included: atorvastatin, ciprofloxacin, and gemfibrozil.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [119 umol/L, range = (62 - 106)], high glucose [13.5 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], high protein [1+, range = NEGATIVE], and high urate [440 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [6.78 mmol/L, range = (2.86 - 8.21), BL =high], high CRP [5.26 mg/L, range = (0 - 3), BL =normal], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 440) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [UNKNOWN CAUSE OF DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 461) the subject experienced death [unknown cause of death]. The event was considered serious for the following reasons: results in death. The event occurred 40 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [50 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [18.56 mmol/L, range = (2.14 - 7.14)], high creatinine [167 umol/L, range = (62 - 106)], high glucose [14.6 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.39 fraction of 1, range = (0.4 - 0.52)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], high leukocytes [4-12 /HPF, range = 0-3], and high urate [726 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** low alkaline phosphatase [36 U/L, range = (40 - 129), BL =normal], low hemoglobin [129 g/L, range = (130 - 175), BL =normal], low magnesium [0.6 mmol/L, range = (0.65 - 1.05), BL =normal], high potassium [5.3 mmol/L, range = (3.3 - 5.1), BL =normal], and normal urine microscopics [normal, range = NORMAL, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 461) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 708) the subject experienced death (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 707 days after the first dose of any study medication.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, amoxicillin/clauvanate(augmentin), antidepressants, atorvastatin, beta blocker, doxycycline, oral corticosteroids, and warfarin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [52 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [8.93 mmol/L, range = (2.86 - 8.21)], high creatinine [125 umol/L, range = (62 - 106)], and high urate [517 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 680), the subject had the following on-study laboratory test results with results different than baseline:** low hematocrit [0.37 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [115 g/L, range = (130 - 177), BL =normal], high leukocytes [15 10^9/L, range = (4.1 - 12.3), BL =normal], and high leukocytes [4-12 /HPF, range = 0-3, BL = missing].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 708) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 788) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 31 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, amoxicillin, analgesic or antipyretic agent, antidepressants, and atorvastatin.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline: high protein [trace, range = NEGATIVE, BL =normal], and high urate [446 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 788) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY FAILURE [RESPIRATORY FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 299) the subject experienced respiratory failure (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 284 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the respiratory failure and up to 30 days prior to event onset included: atorvastatin, azithromycin, and levaquin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [53 mL/min/1.73m2, range = (60 - 9999)], high bilirubin [1+, range = NEGATIVE], high blood urea nitrogen [8.57 mmol/L, range = (2.86 - 8.21)], high creatinine [118 umol/L, range = (62 - 106)], and high lactate dehydrogenase [266 U/L, range = (5 - 250)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 170), the subject had the following on-study laboratory test results with results different than baseline:** high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 299) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): PULSELESS ELECTRICAL ACTIVITY [PULSELESS ELECTRICAL ACTIVITY]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 325) the subject experienced pulseless electrical activity (Grade 4). The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 72 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulseless electrical activity and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [78.86 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [34 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [15.71 mmol/L, range = (2.14 - 7.14)], high creatinine [234 umol/L, range = (62 - 106)], high glucose [7 mmol/L, range = (4.1 - 5.9)], low hematocrit [0.37 fraction of 1, range = (0.4 - 0.52)], low hemoglobin [122 g/L, range = (130 - 175)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high occult blood [trace, range = NEGATIVE], and high urate [642 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [388 IU/L, range = (24 - 250), BL =normal], low erythrocytes [3.6 10^12/L, range = (4.1 - 5.9), BL =normal], and high protein [3+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 325) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): UNEVALUABLE EVENT [UNEVALUABLE EVENT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 127) the subject experienced unevaluable event (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 39 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the unevaluable event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.04 mg/L, range = (0 - 3)], high glucose [6.7 mmol/L, range = (4.6 - 6.4)], and high leukocytes [4-12 /HPF, range = 0-3]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 127) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): TOXICITY TO VARIOUS AGENTS [DRUG TOXICITY - FENTANYL & COCAINE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 670) the subject experienced toxicity to various agents [drug toxicity - fentanyl & cocaine] (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 11 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the toxicity to various agents and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high bilirubin [1+, range = NEGATIVE], high leukocytes [13-30 /HPF, range = 0-3], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 498), the subject had the following on-study laboratory test results with results different than baseline:** normal bilirubin [negative, range = NEGATIVE, BL =high], high blood urea nitrogen [11.42 mmol/L, range = (2.14 - 7.14), BL =normal], high creatinine [126 umol/L, range = (62 - 106), BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 670) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 412) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 75 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [57 mL/min/1.73m2, range = (60 - 9999)], high creatinine [86 umol/L, range = (44 - 80)], high glucose [6.2 mmol/L, range = (4.1 - 5.9)], and high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high calcium [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], high calcium corrected [2.63 mmol/L, range = (2.1 - 2.58), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-8, BL = missing], high hematocrit [0.49 fraction of 1, range = (0.35 - 0.47), BL =normal], and high urate [393 umol/L, range = (143 - 339), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 412) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 711) the subject experienced death. The event was considered serious for the following reasons: results in death. The event occurred 38 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: cefazolin (ancef), ciprofloxacin, gentamicin, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [8.39 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [49 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [143 U/L, range = (40 - 129)], high creatinine [118 umol/L, range = (62 - 106)], high erythrocytes [9-14 /HPF, range = 0-5], low glucose [3.9 mmol/L, range = (4.6 - 6.4)], high leukocytes [12.6 10^9/L, range = (4.1 - 12.3)], high protein [1+, range = NEGATIVE], and high protein [89 g/L, range = (60 - 80)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [171 U/L, range = (4 - 37), BL =normal], high creatine kinase [492 IU/L, range = (20 - 203), BL =normal], normal creatinine [84 umol/L, range = (62 - 106), BL =high], low erythrocytes [3.7 10^12/L, range = (4 - 5.8), BL =normal], normal glucose [5 mmol/L, range = (4.6 - 6.4), BL =low], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5), BL =normal], low hemoglobin [117 g/L, range = (130 - 177), BL =normal], high lactate dehydrogenase [1768 U/L, range = (5 - 250), BL =normal], normal leukocytes [6.5 10^9/L, range = (4.1 - 12.3), BL =high], low platelets [47 10^9/L, range = (140 - 450), BL =normal], and normal protein [69 g/L, range = (60 - 80), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 711) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 335) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 5 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], low thyrotropin [0.15 mU/L, range = (0.55 - 4.78)], high creatinine [123 umol/L, range = (44 - 80)], high glucose [6.6 mmol/L, range = (4.6 - 6.4)], and high urate [404 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 80), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21), BL =normal], high calcium [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], high calcium corrected [2.58 mmol/L, range = (2.2 - 2.55), BL =normal], and normal glucose [5.9 mmol/L, range = (4.6 - 6.4), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 335) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): RESPIRATORY ARREST [RESPIRATORY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 412) the subject experienced respiratory arrest (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 75 days after the last dose of any study medication.

Concomitant medications taken at the onset of the respiratory arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [3.97 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], and high creatinine [117 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [139 U/L, range = (40 - 129), BL =normal], high blood urea nitrogen [10.03 mmol/L, range = (2.86 - 8.21), BL =normal], high direct bilirubin [6 umol/L, range = (0 - 5), BL =normal], low hemoglobin [122 g/L, range = (130 - 177), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], high leukocytes [4-12 /HPF, range = 0-3, BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and high urate [458 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 412) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC ARREST [CARDIAC ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 98) the subject experienced cardiac arrest (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 69 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac arrest and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high creatine kinase [221 IU/L, range = (20 - 203)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], low magnesium [0.6 mmol/L, range = (0.65 - 1.05)], high protein [1+, range = NEGATIVE], and high urate [428 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 98) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): UROSEPSIS [UROSEPSIS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 45) the subject experienced foot fracture [broken foot] (Grade 3) which required surgery and she was subsequently admitted for rehabilitation. On PPD, the subject was hospitalized due to altered mental status, dehydration, and urinary retention after changes to her medications of insulin regimen and furosemide dosing were made. Her primary care physician was not able to dictate medical management while she was in the rehabilitation facility for her knee and ankle rehabilitation post-surgery. On PPD (Day 68) the subject experienced shock [shock (excl traumatic and specific cause)] (Grade 3). Antibiotics were started, but later discontinued as blood and urine cultures were negative. The subject was suspected to have adrenal insufficiency with severe hypoglycemia, hyperkalemia, hypotension, and hyponatremia, and was treated with corticosteroids. The subject developed cryptogenic cirrhosis with elevated ammonia and hypoalbumenia. On PPD the acute renal and liver dysfunction was considered resolved and the subject was transferred back to the rehab facility. On PPD (Day 104) the subject experienced urosepsis (Grade 1). The event was considered serious for the following reasons: results in death. The event occurred 74 days after the last dose of any study medication.

Concomitant medications taken at the onset of the urosepsis and up to 30 days prior to event onset included: rosuvastatin, paracetamol, furosemide, amlodipine, acetylsalicylic acid, benazepril, gabapentin, glimepiride, hydralazine, oxycodone, insulin, metoprolol, omeprazole, promethazine, terazosin.

The subject had the following abnormal laboratory test results at baseline: high CRP [6.15 mg/L, range = (0 - 3)], high aspartate aminotransferase [36 U/L, range = (4 - 31)], high bilirubin [1+, range = NEGATIVE], high direct bilirubin [7 umol/L, range = (0 - 5)], high glucose [7.3 mmol/L, range = (4.6 - 6.4)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], high lactate dehydrogenase [261 U/L, range = (5 - 250)], high leukocytes [tntc /HPF, range = 0-12], low

platelets [121 10^9/L, range = (140 - 450)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 104) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 662) the subject experienced death (Grade 4). The event was considered serious for the following reasons; results in death. The event occurred 72 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and valcyclovir.

The subject had the following abnormal laboratory test results at baseline: high CRP [17.61 mg/L, range = (0 - 3)], high erythrocytes [15-30 /HPF, range = 0-8], low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], high leukocytes [tntc /HPF, range = 0-12], high occult blood [trace, range = NEGATIVE], high protein [3+, range = NEGATIVE], high alkaline phosphatase [109 U/L, range = (35 - 104)], high blood urea nitrogen [10.71 mmol/L, range = (2.86 - 8.21)], high creatinine [112 umol/L, range = (44 - 80)], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.4)], and high urate [375 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** normal alkaline phosphatase [81 U/L, range = (35 - 104), BL =high], normal erythrocytes [4 10^12/L, range = (3.8 - 5.4), BL =low], normal erythrocytes [0-5 /HPF, range = 0-8, BL =high], normal leukocytes [0-3 /HPF, range = 0-12, BL =high], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 662) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 955) the subject experienced death. The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 16 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, dicloxacillin, influenza vaccine, levaquin, and moxifloxacin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.47 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], high calcium [2.85 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.9 mmol/L, range = (2.2 - 2.55)], high creatinine [113 umol/L, range = (62 - 106)], high protein [1+, range = NEGATIVE], and high urate [482 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 848), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [192 U/L, range = (40 - 129), BL =normal], high blood urea nitrogen [16.67 mmol/L, range = (2.86 - 8.21), BL =normal], normal calcium [2.4 mmol/L, range = (2.2 - 2.55), BL =high], normal calcium corrected [2.4 mmol/L, range = (2.2 - 2.55), BL =high], low glucose [4.5 mmol/L, range = (4.6 - 6.4), BL =normal], low hemoglobin [116 g/L, range = (130 - 177), BL =normal], normal protein [negative, range = NEGATIVE, BL =high], and normal urate [286 umol/L, range = (202 - 416), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 955) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): GUN SHOT WOUND [GUN SHOT WOUND]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 572) the subject experienced gun shot wound (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 67 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the gun shot wound and up to 30 days prior to event onset included: fenofibrate, and simvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high leukocytes [4-12 /HPF, range = 0-3], and low platelets [138 10^9/L, range = (140 - 450)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal leukocytes [0-3 /HPF, range = 0-3, BL =high], normal platelets [157 10^9/L, range = (140 - 450), BL =low], and high protein [1+, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 572) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): LUNG NEOPLASM MALIGNANT [LUNG CANCER]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 367) the subject experienced lung neoplasm malignant [lung cancer]. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 163 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung neoplasm malignant and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [54 mL/min/1.73m2, range = (60 - 9999)], and high creatinine [112 umol/L, range = (62 - 106)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 175), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [103 umol/L, range = (62 - 106), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 367) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 833) the subject experienced death. The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 18 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, beta blocker, clopidogrel, glycemic control medication, insulin, and vitamin supplements.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.44 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [45 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [18.92 mmol/L, range = (2.14 - 7.14)], high creatinine [170 umol/L, range = (62 - 106)], high glucose [15.8 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high urate [553 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 815), the subject had the following on-study laboratory test results with results different than baseline:** high creatine kinase [287 IU/L, range = (24 - 250), BL =normal], and normal urate [375 umol/L, range = (202 - 416), BL =high].

The investigator's opinion of the relationship between the event and IP and event and statin was not reported. The event ended on PPD (Day 833).

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH NOS]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 535) the subject experienced death [death nos]. The event was considered serious for the following reasons: results in death. The event occurred 512 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [58 mL/min/1.73m2, range = (60 - 9999)], high lactate dehydrogenase [252 U/L, range = (5 - 250)], high creatine kinase [287 IU/L, range = (20 - 203)], high creatinine [121 umol/L, range = (62 - 106)], high leukocytes [4-12 /HPF, range = 0-3], high protein [1+, range = NEGATIVE], and high urate [452 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 535) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 531) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 141 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.48 mg/L, range = (0 - 3)], high glucose [16.8 mmol/L, range = (4.1 - 5.9)], high glucose [3+, range = NEGATIVE], high HbA1c [0.11 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 390), the subject had the following on-study laboratory test results with results different than baseline:** low bilirubin [<2 umol/L, BL =normal], high blood urea nitrogen [8.21 mmol/L, range = (2.14 - 7.14), BL =normal], normal CRP [0.23 mg/L, range = (0 - 3), BL =high], high protein [88 g/L, range = (60 - 80), BL =normal], and high urate [446 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 531) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [DEATH DUE TO STROKE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Renal)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 561) the subject experienced cerebrovascular accident [death due to stroke] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, is life threatening, and other medically important serious event. The event occurred 21 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: bactrim, bactrim ds, ceftriaxone, and rosuvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [32 mL/min/1.73m2, range = (60 - 9999)], high alkaline phosphatase [119 U/L, range = (35 - 104)], high blood urea nitrogen [12.14 mmol/L, range = (2.86 - 8.21)], high creatinine [177 umol/L, range = (44 - 80)], low erythrocytes [3.6 10^12/L, range = (3.8 - 5.4)], high glucose [9.1 mmol/L, range = (4.6 - 6.4)], high glucose [2+, range = NEGATIVE], low hematocrit [0.33 fraction of 1, range = (0.33 - 0.46)], low hemoglobin [108 g/L, range = (110 - 161)], high HbA1c [0.1 fraction of 1, range = (0.04 - 0.06)], low leukocytes [3.9 10^9/L, range = (4.1 - 12.3)], high potassium [5.4 mmol/L, range = (3.3 - 5.1)], high protein [1+, range = NEGATIVE], and high urate [357 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 511), the subject had the following on-study laboratory test results with results different than baseline:** high aspartate aminotransferase [32 U/L, range = (4 - 31), BL =normal], low calcium [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], low calcium corrected [2.18 mmol/L, range = (2.2 - 2.55), BL =normal], normal hematocrit [0.34 fraction of 1, range = (0.33 - 0.46), BL =low], normal hemoglobin [110 g/L, range = (110 - 161), BL =low], normal leukocytes [5.5 10^9/L, range =

(4.1 - 12.3), BL =low], high magnesium [1.13 mmol/L, range = (0.65 - 1.05), BL =normal], high protein [82 g/L, range = (60 - 80), BL =normal], and low sodium [133 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 561) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 9) the subject experienced adenocarcinoma pancreas [adenocarcinoma in pancreas] (Grade 4). On PPD (Day 218) the subject died due to the event. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 217 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [7.85 mmol/L, range = (2.14 - 7.14)], high glucose [6.9 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], low platelets [139 10^9/L, range = (140 - 450)], and high specific gravity [1.04, range = (1 - 1.04)]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 218) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 654) the subject experienced malignant peritoneal neoplasm [peritoneal carcinoma] (Grade 3) and on PPD (Day 802) the subject died. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 157 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and valaciclovir.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline: high bilirubin [2+, range = NEGATIVE, BL =normal], high protein [1+, range = NEGATIVE, BL =normal], low protein [57 g/L, range = (60 - 80), BL =normal], and high specific gravity [1.04, range = (1 - 1.04), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 802) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 502) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin, and staklox.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [55 mL/min/1.73m2, range = (60 - 9999)], high creatinine [118 umol/L, range = (62 - 106)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 337), the subject had the following on-study laboratory test results with results different than baseline:** high alkaline phosphatase [133 U/L, range = (40 - 129), BL =normal], normal creatinine [105 umol/L, range = (62 - 106), BL =high], high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 502) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 522) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 19 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: analgesic or antipyretic agent, angiotensin receptor blocker, atorvastatin, beta blocker, colistin, enoxaparin, glycemic control medication, insulin, meropenem, and tazobactam piperacilline.

The subject had the following abnormal laboratory test results at baseline: high blood urea nitrogen [9.28 mmol/L, range = (2.86 - 8.21)], high glucose [11.6 mmol/L, range = (4.6 - 6.4)], high glucose [trace, range = NEGATIVE], low hemoglobin [129 g/L, range = (130 - 177)], high HbA1c [0.08 fraction of 1, range = (0.04 - 0.06)], and high protein [1+, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 475), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [31 g/L, range = (35 - 52), BL =normal], low calcium [2.08 mmol/L, range = (2.2 - 2.55), BL =normal], high creatinine [109 umol/L, range = (62 - 106), BL =normal], normal glucose [5.4 mmol/L, range = (4.6 - 6.4), BL =high], low hematocrit [0.35 fraction of 1, range = (0.37 - 0.5), BL =normal], and high urate [428 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 522) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): SUDDEN DEATH [SUDDEN DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Sudden Cardiac)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 370) the subject experienced sudden death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 34 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the sudden death and up to 30 days prior to event onset included: amoxicillin, atorvastatin, and ciclopiroxolamine.

The subject had the following abnormal laboratory test results at baseline: high calcium [2.83 mmol/L, range = (2.2 - 2.55)], high calcium corrected [2.83 mmol/L, range = (2.2 - 2.55)], and high hematocrit [0.51 fraction of 1, range = (0.37 - 0.5)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 168), the subject had the following on-study laboratory test results with results different than baseline:** high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be related to IP and not related to statin. The event ended on PPD (Day 370) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): CARDIO-RESPIRATORY ARREST [CARDIORESPIRATORY ARREST]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Non-Cardiovascular (Pulmonary)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 628) the subject experienced cardio-respiratory arrest [cardiorespiratory arrest]. The event was considered serious for the following reasons: results in death. The event occurred 441 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardio-respiratory arrest and up to 30 days prior to event onset included: ampicillin, atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [53.74 mg/L, range = (0 - 3)], high alkaline phosphatase [200 U/L, range = (40 - 129)], high occult blood [trace, range = NEGATIVE], and low urate [161 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 187), the subject had the following on-study laboratory test results with results different than baseline:** low albumin [34 g/L, range = (35 - 52), BL =normal], and normal occult blood [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 628) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBROVASCULAR ACCIDENT [CEREBROVASCULAR ACCIDENT]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Stroke)

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 342) the subject experienced cerebrovascular accident (Grade 4). The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebrovascular accident and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [20.25 mg/L, range = (0 - 3)], high thyrotropin [6.01 mU/L, range = (0.55 - 4.78)], high alkaline phosphatase [111 U/L, range = (35 - 104)], high creatinine [87 umol/L, range = (44 - 80)], low hemoglobin [109 g/L, range = (110 - 161)], high HbA1c [0.09 fraction of 1, range = (0.04 - 0.06)], and low magnesium [0.6 mmol/L, range = (0.65 - 1.05)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** high bilirubin [1+, range = NEGATIVE, BL =normal], normal creatinine [74 umol/L, range = (44 - 80), BL =high], high glucose [6.8 mmol/L, range = (4.6 - 6.4), BL =normal], high protein [trace, range = NEGATIVE, BL =normal], and low sodium [134 mmol/L, range = (135 - 147), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 342) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Infection; Includes Sepsis)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 540) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 119 days after the last dose of any study medication. No treatment medications were reported for the event.

There were no concomitant medications recorded for this subject at the onset of the SAE.

The subject had the following abnormal laboratory test results at baseline: high CRP [5.37 mg/L, range = (0 - 3)], high blood urea nitrogen [8.93 mmol/L, range = (2.14 - 7.14)], high creatinine [116 umol/L, range = (62 - 106)], high glucose [6.6 mmol/L, range = (4.1 - 5.9)], high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)], high protein [3+, range = NEGATIVE], and high urate [464 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 344), the subject had the following on-study laboratory test results with results different than baseline:** high leukocytes [13.2 10^9/L, range = (4.1 - 12.3), BL =normal], and high potassium [5.2 mmol/L, range = (3.3 - 5.1), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 540) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 706) the subject experienced death. The event was considered serious for the following reasons: persistent or significant disability/incapacity, results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 111 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: atorvastatin.

The subject had the following abnormal laboratory test results at baseline: low glomerular filtration rate, estimated [44 mL/min/1.73m2, range = (60 - 9999)], high creatinine [95 umol/L, range = (44 - 80)], high protein [trace, range = NEGATIVE], and high urate [416 umol/L, range = (143 - 339)]. **On the closest laboratory test results day on or prior to the start of the event (**PPD **Day 505), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [12.82 mmol/L, range = (2.86 - 8.21), BL =normal], and normal protein [negative, range = NEGATIVE, BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 706) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): PULMONARY OEDEMA [PULMONARY EDEMA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 753) the subject experienced pulmonary oedema [pulmonary edema] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 80 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the pulmonary oedema and up to 30 days prior to event onset included: atorvastatin, and ciprofloxacin.

The subject had the following abnormal laboratory test results at baseline: high CRP [23.95 mg/L, range = (0 - 3)], low glomerular filtration rate, estimated [59 mL/min/1.73m2, range = (60 - 9999)], low erythrocytes [3.8 10^12/L, range = (4 - 5.8)], low hemoglobin [125 g/L, range = (130 - 177)], and high lactate dehydrogenase [300 U/L, range = (5 - 250)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 673), the subject had the following on-study laboratory test results with results different than baseline:** high blood urea nitrogen [9.71 mmol/L, range = (2.86 - 8.21), BL =normal], high creatinine [149 umol/L, range = (62 - 106), BL =normal], low hematocrit [0.37 fraction of 1, range = (0.37 - 0.5), BL =normal], high protein [1+, range = NEGATIVE, BL =normal], and high urate [488 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 753) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CARDIAC FAILURE ACUTE [ACUTE DECOMPENSATED HEART FAILURE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Heart Failure)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 314) the subject experienced cardiac failure acute [acute decompensated heart failure] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 9 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cardiac failure acute and up to 30 days prior to event onset included: atorvastatin, and ciprofloxacin.

The subject had the following abnormal laboratory test results at baseline: high CRP [7.52 mg/L, range = (0 - 3)], high blood urea nitrogen [10.35 mmol/L, range = (2.86 - 8.21)], high creatine kinase [257 IU/L, range = (20 - 203)], high HbA1c [0.06 fraction of 1, range = (0.04 - 0.06)], and high urate [630 umol/L, range = (202 - 416)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 169), the subject had the following on-study laboratory test results with results different than baseline:** normal blood urea nitrogen [7.5 mmol/L, range = (2.86 - 8.21), BL =high], normal creatine kinase [149 IU/L, range = (20 - 203), BL =high], high creatinine [107 umol/L, range = (62 - 106), BL =normal], normal erythrocytes [0-5 /HPF, range = 0-5, BL = missing], high leukocytes [tntc /HPF, range = 0-3, BL =normal], and high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 314) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: AMG 145
Actual Arm: AMG 145

Death Endpoint (coded term [reported term]): LUNG CARCINOMA CELL TYPE UNSPECIFIED STAGE II [CARCINOMA LUNG CELL TYPE UNSPECIFIED STAGE II]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Non-Cardiovascular Death	Death - Non-Cardiovascular (Malignancy)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 21) the subject experienced lung carcinoma cell type unspecified stage ii [carcinoma lung cell type unspecified stage ii] (Grade 3) and PPD (Day 77) the subject died due to the event. The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 61 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the lung carcinoma cell type unspecified stage ii and up to 30 days prior to event onset included: ACE inhibitor, acetylsalicylic acid, analgesic or antipyretic agent, atorvastatin, beta blocker, and clopidogrel.

The subject had the following abnormal laboratory test results at baseline: high CRP [24.81 mg/L, range = (0 - 3)], high leukocytes [14 10^9/L, range = (4.1 - 12.3)], high platelets [562 10^9/L, range = (140 - 450)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event, the subject had no on-study laboratory test results with results different than baseline.**

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 77) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): INTESTINAL ISCHAEMIA [EXTENSIVE MESENTERIC ISCHEMIA]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Cardiovascular (Due To Other Cardiovascular Causes) (Mesenteric Ischemia)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 154) the subject experienced intestinal ischaemia [extensive mesenteric ischemia] (Grade 4). The event was considered serious for the following reasons: results in death, and requires or prolongs hospitalization. The event occurred 70 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the intestinal ischaemia and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [4.4 mg/L, range = (0 - 3)], high creatine kinase [478 IU/L, range = (24 - 250)], high creatinine [109 umol/L, range = (62 - 106)], high glucose [6.5 mmol/L, range = (4.1 - 5.9)], and high HbA1c [0.07 fraction of 1, range = (0.04 - 0.06)]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 84), the subject had the following on-study laboratory test results with results different than baseline:** normal creatinine [95 umol/L, range = (62 - 106), BL =high].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 154) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): CEREBRAL HAEMORRHAGE [INTRACEREBRAL HEMORRHAGE]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Cardiovascular Death	Death - Non-Cardiovascular (Trauma)

Subject PPD was a P -year-old PPD male who was participating in Study 20110118. His medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 127) the subject experienced cerebral haemorrhage [intracerebral hemorrhage] (Grade 4). The event was considered serious for the following reasons: results in death, requires or prolongs hospitalization, and is life threatening. The event occurred 29 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the cerebral haemorrhage and up to 30 days prior to event onset included: atorvastatin, and atorvastatin.

The subject had the following abnormal laboratory test results at baseline: high CRP [9.2 mg/L, range = (0 - 3)], low thyroxine [11.2 pmol/L, range = (11.5 - 22.7)], low glomerular filtration rate, estimated [39 mL/min/1.73m2, range = (60 - 9999)], high blood urea nitrogen [12.5 mmol/L, range = (2.86 - 8.21)], high creatinine [149 umol/L, range = (62 - 106)], low erythrocytes [3.7 10^12/L, range = (4 - 5.8)], low hematocrit [0.36 fraction of 1, range = (0.37 - 0.5)], low hemoglobin [117 g/L, range = (130 - 177)], high potassium [5.2 mmol/L, range = (3.3 - 5.1)], and high protein [trace, range = NEGATIVE]. **On the closest laboratory test results day on or prior to the start of the event (PPD Day 84), the subject had the following on-study laboratory test results with results different than baseline:** high alanine aminotransferase [105 U/L, range = (4 - 41), BL =normal], high alkaline phosphatase [172 U/L, range = (40 - 129), BL =normal], high aspartate aminotransferase [57 U/L, range = (4 - 37), BL =normal], high bilirubin [24 umol/L, range = (3 - 21), BL =normal], high direct bilirubin [7 umol/L, range = (0 - 5), BL =normal], and high urate [488 umol/L, range = (202 - 416), BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event

ended on PPD (Day 127) with an outcome of fatal.

Study ID: 20110118
Subject: PPD
Randomized Arm: PLACEBO
Actual Arm: PLACEBO

Death Endpoint (coded term [reported term]): DEATH [DEATH]

Subject ID	Adjudication	Adjudicated cause of death
PPD	Undetermined Death	Death - Undetermined

Subject PPD was a P -year-old PPD female who was participating in Study 20110118. Her medical history included PPD

The subject received the first dose of investigational product (IP) on PPD (Day 1). On PPD (Day 272) the subject experienced death (Grade 4). The event was considered serious for the following reasons: results in death. The event occurred 26 days after the last dose of any study medication. No treatment medications were reported for the event.

Concomitant medications taken at the onset of the death event and up to 30 days prior to event onset included: acetylsalicylic acid, analgesic or antipyretic agent, angiotensin receptor blocker, antidepressants, atorvastatin, beta blocker, and nystatin + zinc oxide.

The subject had no abnormal laboratory test results at baseline. On the closest laboratory test results day on or prior to the start of the event (PPD Day 164), the subject had the following on-study laboratory test results with results different than baseline: high protein [trace, range = NEGATIVE, BL =normal].

The investigator considered the event to be not related to IP and not related to statin. The event ended on PPD (Day 272) with an outcome of fatal.

14.6.2.2 SAE EOS Narratives

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Myocardial infarction	Myocardial infarction (Myocardial infarction)	PPD ---

Case Narrative : Information received on PPD This P year old male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and experienced a myocardial infarction [PT: myocardial infarction].

No historical medical condition was reported. The subject's current medical condition included dyslipidemia. The subject's concomitant medications included Atorvastatina (atorvastatin calcium), Atenolol (atenolol), Losartan (losartan), Furosemida (furosemide), and Amlodipina (amlodipine). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug an unknown date. On PPD the subject was hospitalized because of myocardial infarction without ST elevation. Troponin T level was 315.4 pg/ml. Circumflex angioplasty was performed with stent. The subject's last dose of blinded investigational drug prior to the event was unknown. The outcome of the event myocardial infarction was reported as resolved on PPD and on the same day, the subject as discharged from the hospital. Action taken with blinded investigational drug was reported as unknown for the event myocardial infarction.

The investigator reported that the event myocardial infarction was not related to blinded investigational drug and to the device.

Study Drug : placebo Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	Yes	No	---	UNK UNK, q2wk	Subcutaneous	q2wk	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Pancreatitis	Pancreatitis (Pancreatitis)	PPD ---

Case Narrative : Initial Receipt Date = PPD .

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This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed pancreatitis.

The subject's medical history included PPD .

The subject received the first dose of blinded investigational study drug on an unknown date. The subject completed end of study on PPD . PPD . The subject's last dose of blinded investigational study drug prior to the event was unknown.

The investigator reported that there was a reasonable possibility that the event pancreatitis was related to blinded investigational study drug; however it was not related to the device or to the study conduct.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Mild cardial decompression	Cardiac failure (Decompensation cardiac)	PPD (22 days)
suspected infective exacerbation of chronic pulmonary disease	Infective exacerbation of chronic obstructive airways disease (Infective exacerbation of chronic obstructive airways disease)	PPD (22 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Mild cardial decompression [PT: Cardiac failure] and exacerbated COPD [PT: Chronic obstructive pulmonary disease].

The subject's historical medical conditions included PPD . The subject's current medical condition included Dyslipidemia, COPD (chronic obstructive pulmonary disease), Asthma Bronchial, Diabetes Mellitus Type 2, Hyperlipidemia, Coronary heart disease, Chronic Renal Insufficiency and Asthma. Surgical procedure included Implantable Cardioverter-Defibrillator

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implant. The subject did not have any known PPD . Concomitant medications included Prasugrel (Prasugrel), Fluticasone W/Salmeterol (Fluticasone, Salmeterol).

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug was on PPD . On PPD , the subject completed end of study visit. PPD

The investigator reported that the events Cardiac failure and Chronic obstructive pulmonary disease were not related to blinded investigational drug and to the device.

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ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that there was not a reasonable possibility that the event suspected infective exacerbation of chronic pulmonary disease was related to blinded investigational study drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
NSTEMI	Acute myocardial infarction (Non ST segment elevation myocardial infarction)	PPD --

Case Narrative : Initial Receipt Date = PPD .

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed NSTEMI [PT: Acute myocardial infarction].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. Concomitant medications included Atorvastatin (Atorvastatin), Thrombo ASS (Acetylsalicylic Acid), Metoprolol (Metoprolol), Pantoloc (Pantoprazole Sodium Sesquihydrate), Concor (Bisoprolol Fumarate), Ramipril (Ramipril), Brilique (Ticagrelor), Atozet (Atorvastatin Calcium, Ezetimibe), Lendorm (Brotizolam), and Gastrozol (Omeprazole).

The subject received the first dose of blinded investigational study drug on an unknown date. The subject's last dose of blinded investigational drug prior to the event was on an unknown date. On PPD , the subject underwent percutaneous coronary intervention (PCI) of left anterior descending artery (LAD). The end of the study was completed on PPD

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PPD

The investigator reported that the event Acute myocardial infarction was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject's coronary risk factors included medical history of PPD

PPD

Study Drug :

Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK, q2wk	Subcutaneous	q2wk	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Coronary stenting (PCI)	Percutaneous coronary intervention (Percutaneous coronary intervention)	PPD (11 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and underwent Coronary stenting (PCI) [PT: Percutaneous coronary intervention].

The subject's historical medical condition included PPD. The subject's current medical condition included dyslipidaemia, hypertension, hyperlipidemia, and hyperlipoproteinemia. Historical procedure included PPD. Concomitant medications included Atorvastatin (Atorvastatin), Nebivolol (Nebivolol), Thrombo Ass (Acetylsalicylic Acid), and Euthyrox (Levothyroxine Sodium).

The subject received the first dose of blinded investigational study drug on an unknown date. The subject received the last dose of blinded investigational study drug on PPD On an unknown date, the subject experienced exertional dyspnea. The subject had PPD. On PPD, the subject was hospitalized. On the same day, laboratory test showed troponin I 6.2 ng/l. On PPD laboratory test showed troponin I 15.02 ng/l. On PPD laboratory test showed troponin I 31.98 ng/l. During the hospitalization, angiography showed three vascular disease with stenosis in left anterior descending (LAD), 70% stenosis in circumflex (Cx), 99% stenosis in right coronary artery (RCA) (middle), and 99% in stent restenosis to distal RCA. On PPD the subject underwent percutaneous coronary intervention (PCI) with coronary stenting. There were no complications of the procedure. The outcome of the event Percutaneous coronary intervention was reported as Resolved. The event Percutaneous coronary intervention was resolved on PPD The subject completed end of study (EOS) visit on PPD.

The investigator reported that the event Percutaneous coronary intervention was not related to blinded investigational study drug and to the device.

CORRECTION DATED ON PPD : This new version was created to correct EOS date from PPD to PPD.

Study Drug :

Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Pancreatic necrosis	Pancreatic necrosis (Pancreatic necrosis)	PPD (42 days)

Case Narrative : Initial Receipt Date = PPD

This P years old, PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease, developed Pancreatic necrosis [PT: Pancreatic necrosis].

The subject's historical medical condition included PPD . The subject's current medical condition included dyslipidemia, hypertension, metabolic syndrome, gastritis, esophagitis. Concomitant medications included Atorvastatin (Atorvastatin), Acid Acetylsalicylic (Acetylsalicylic Acid), Carvedilol (Carvedilol), Hydrochlorothiazide (Hydrochlorothiazide), Omeprazole (Omeprazole).

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject completed the study. P P D The subject received the last dose of blinded investigational study drug prior to the event on PPD

The investigator reported that the event Pancreatic necrosis was not related to blinded investigational drug or device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Tracheobronchitis	Tracheobronchitis (Tracheobronchitis)	PPD (21 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Tracheobronchitis [PT: Tracheobronchitis].

The subject's historical medical condition included PPD. The subject's current medical condition included Dyslipidaemia, Diabetic, and Hypertension. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD. On PPD, the subject had myocardial infarction (previously reported as PEP). The subject's end of study visit was performed on PPD. On PPD

The subject's last dose of blinded investigational drug prior to the event was on PPD. PPD

The investigator reported that the event Tracheobronchitis was not related to blinded investigational drug, device, and to the study conduct.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Heart failure decompensated	Cardiac failure (Decompensated heart failure)	PPD (21 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, had Heart failure decompensated [PT: Cardiac failure].

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No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . On an unknown date, the subject was hospitalized for unknown reason. On PPD , the subject completed end of study. PPD The subject's last dose of blinded investigational drug prior to the event was on PPD

The investigator reported that the event Cardiac failure was not related to blinded investigational study drug and to device.

Version created in error on PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
TIA	Transient ischaemic attack (TIA)	PPD ---

Case Narrative : Initial Receipt Date = PPD

This PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed TIA [PT: Transient ischaemic attack].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD , the subject completed the study. P P D The subject's last dose of blinded investigational drug prior to the event was on an unknown date. PPD

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PPD .

The investigator reported that the event Transient ischaemic attack was not related to blinded investigational drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
LFTs increased	Liver function test increased (LFTs raised)	PPD (1 day)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed LFTs increased.

The subject's medical history included PPD . Previous treatment for the condition under study was not provided. Concomitant medications included ASA (acetylsalicylic acid), enalapril and atenolol.

The subject received the first dose of blinded investigational study drug on PPD . Approximately two months, two weeks and two days later on PPD , the subject developed LFT's increased. On the same day, the subject came for end of study (EOS) visit in stable clinical condition. The subject did not have flu or any illness. Physical examination was unremarkable. The subject did not make any changes in concomitant medications and was recommended to stop atorvastatin. The outcome of the event LFTs increased was reported as ongoing. The subject's last dose of blinded investigational study drug was on PPD Blinded investigational study drug was discontinued due to the end of study.

The investigator reported that there was not a reasonable possibility that the event LFTs increased was related to blinded investigational study drug or device. The investigator considered atorvastatin as co-suspect.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

At the time of the reported event, the subject did not visit to the site for the retest, therefore end of study (EOS) visit was considered as PPD : PPD .

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK ml, UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
stroke	Cerebrovascular accident (Stroke)	PPD (76 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed life threatening and fatal stroke.

The subject's medical history included PPD

No previous treatment for the condition under the study was reported. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject had fully withdrawn the consent from participation in study. PPD

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The investigator reported that there was not a reasonable possibility that the life threatening and fatal event stroke, was related to blinded investigational study drug and to device.

Study Drug : placebo

Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
STROKE	Cerebrovascular accident (Stroke)	PPD (267 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed fatal event stroke.

The subject's medical history included PPD . Previous treatment for the condition under study was not reported. Concomitant medications were not reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject received last dose of blinded investigational study drug on PPD On PPD , the subject withdrew consent and completed study (end of study). PPD

The investigator reported that there was not a reasonable possibility that the fatal event stroke was related to blinded investigational study or to the device.

Study Drug : AMG 145

Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
invasive adenocarcinoma of cecal mass	Adenocarcinoma of colon (Adenocarcinoma of colon)	PPD (14 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed cecal mass - likely adenocarcinoma.

The subject's medical history included dyPPD . The subject had no known allergies. Previous treatment for the condition under study was not provided. Concomitant medications included Lipitor (atorvastatin calcium), Diamicron (gliclazide), Bystolic (nebivolol hydrochloride), Coversyl (perindopril erbumine), and Lyrica (pregabalin).

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study on PPD . PPD . The subject received the last dose of blinded investigational study drug prior to the event on PPD .

For the event cecal mass - likely adenocarcinoma, as reported causality for blinded investigational study drug and device were not provided by the investigator. None of the concomitant medications were considered as co-suspect.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that there was not a reasonable possibility that the event cecal mass - likely adenocarcinoma was related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

The investigator reported that there was not a reasonable possibility that the event invasive adenocarcinoma of cecal mass was related to blinded investigational study drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Angina pectoris	Angina pectoris (Angina pectoris)	PPD (17 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and experienced angina pectoris.

The subject's medical history included PPD . Concomitant medications included clopidogrel, Aspirin enteric coated (acetylsalicylic acid), atorvastatin calcium, bisoprolol fumarate, isosorbide mononitrate, Pantoprazole sodium enteric coated (pantoprazole sodium sesquihydrate), and diltiazem hydrochloride.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational study drug was on PPD . The subject's end of study visit was performed on PPD PPD

The investigator reported that there was not a reasonable possibility that the event angina pectoris was related to blinded investigational study drug or to the device.

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ADDITIONAL INFORMATION RECEIVED ON PPD : The subject's additional medical history included PPD The subject did not have medical history of diabetes mellitus (DM). The subject did not experience any other serious adverse event (SAE) other than reported SAE angina pectoris.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Unstable angina	Angina unstable (Unstable angina)	PPD (63 days)

Case Narrative : Information received on PPD , this P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed unstable angina [PT: angina unstable].

The subject's historical medical condition included PPD . The subject's current medical condition included dyslipidemia, New York Heart Association class II, and coronary artery disease. No concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study visit on PPD . P P D

The investigator reported that the event angina unstable was not related to blinded investigational drug and to the device.

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Acute gastric mucosa	Gastric mucosal lesion (Acute gastric mucosal lesion)	PPD (11 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed acute gastric mucosa.

The subject's medical history included PPD . Previous treatment for the condition under study and concomitant medications were not reported.

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject completed the study. PPD The subject's last dose of blinded investigational study drug prior to the onset of the event was on PPD .

The investigator reported that there was not a reasonable possibility that the event acute gastric mucosa was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Diabetes mellitus	Diabetes mellitus (Diabetes mellitus)	PPD (30 days)

Case Narrative : Initial Receipt Date = PPD

This P year old female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed diabetes mellitus [PT: diabetes mellitus].

The subject's historical medical condition included PPD. The subject's current medical condition included dyslipidemia, coronary heart disease, hypertension, diabetes mellitus, diabetic retinopathy, kidney stones and arterial sclerosis of lower limbs. Concomitant medication included unspecified statin drug. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. The subject completed the end of study on PPD. PPD

The subject's last dose of blinded investigational drug prior to the event was on PPD. PPD

The investigator reported that the event diabetes mellitus was not related to blinded investigational drug, statin, to the device or to the study conduct.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
acute coronary syndrome	Acute coronary syndrome (Acute coronary syndrome)	PPD (74 days)

Case Narrative : Information received on PPD. This P year old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed acute coronary syndrome [PT: acute coronary syndrome].

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No historical medical condition was reported. The subject's current medical condition included dyslipidemia. No concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on unknown date. The subject's last dose of blinded investigational drug was on PPD. The subject completed end of study (EOS) visit on PPD PPD

The investigator reported that the event acute coronary syndrome was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject received the first dose of blinded investigational study drug on PPD. Additional medical history included PPD. The subject did not have any other medical history. During hospitalization, electrocardiogram (ECG) showed 0.05 MV V4-V6 leads ST level down and low or inverted T wave. Creatine kinase (CK-MB) fraction and serial troponin levels were not performed. The investigator clarified that the subject did not experience any clinical symptoms compatible with myocardial infarction or stable angina leading to diagnosis of the reported event.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
hospital for Hypertension	Hypertension (Hypertension)	PPD (41 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and was in hospital for hypertension.

The subject's medical condition included PPD. Concomitant medications included atorvastatin, bisoprolol fumarate, perindopril, nifedipine, cilostazol, and clopidogrel bisulfate.

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The subject received the first dose of blinded investigational study drug on unknown date. The subject completed the end of study visit on PPD PPD . The subject received the last dose of blinded investigational study drug prior to the event on unknown date.

The investigator reported that there was not a reasonable possibility that the event hospital for hypertension was related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD The subject signed the informed consent form on PPD . The subject received the first dose of blinded investigational study drug on PPD On PPD , the subject received last dose of investigational study drug. The subject was treated with an antiplatelet drug, antihypertensive therapy, hypoglycemic therapy, lipid-lowering therapy with improvement in microcirculation treatment. The investigator reported that the subject felt better after the treatment.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
erysipelas (inflammatory disease with redness of skin)	Erysipelas (Erysipelas)	PPD (24 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed erysipelas (inflammatory disease with redness of skin).

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The subject's medical history included PPD . Previous treatment for condition under study included atorvastatin. Concomitant medication reported included candesartan, Aspirin (acetylsalicylic acid), and "beta-block".

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational study drug was on PPD On PPD , the subject ended the study and the subject was in follow up period after study end. PPD

The investigator reported that there was not a reasonable possibility that the event erysipelas (inflammatory disease with redness of skin) was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that there was a reasonable possibility that the event erysipelas (inflammatory disease with redness of skin) was related to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that there was not a reasonable possibility that the event erysipelas (inflammatory disease with redness of skin) was related to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
PULMONARY INFECTION	Respiratory tract infection (Respiratory infection)	PPD (69 days)
UNSTABLE ANGINA	Angina unstable (Unstable angina)	PPD (69 days)
WORSENING CORONARY HEART DISEASE	Coronary artery disease (Coronary heart disease)	PPD (0 min)

Case Narrative : Information received on PPD. This P year old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed a pulmonary infection [PT: respiratory tract infection], coronary heart disease [PT: coronary artery disease] and unstable angina [PT: angina unstable].

The subject's historical medical condition included PPD. The subject's current medical condition included dyslipidemia, type 2 diabetes mellitus and hypertension. The subject's concomitant medications included Aspirin (acetylsalicylic acid), Atorvastatin (atorvastatin), "felike capsule", Furosemide (furosemide), "songstenyangxin capsule", Irbesartan (irbesartan) and Insulin (insulin). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. The subject completed the study on PPD. On PPD

The investigator reported that the events angina unstable, respiratory tract infection, and coronary artery disease were not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The subject's last dose of blinded investigational drug was on PPD.

The investigator reported that the event coronary artery disease was not related to blinded investigational drug or to the device.

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Coronary heart disease worsened	Coronary artery disease (Coronary heart disease)	PPD
unstable angina	Angina unstable (Unstable angina)	PPD

Case Narrative : Information received on PPD. This P year old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed coronary heart disease [PT: coronary artery disease] and unstable angina [PT: angina unstable].

The subject's historical medical condition included PPD. The subject's current medical condition included dyslipidemia. The subject's concomitant medications included Aspirin (acetylsalicylic acid) and Atorvastatin (atorvastatin). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. The subject completed the end of study on PPD.
PPD
The subject's last dose of blinded investigational drug prior to the event was on an unknown date. PPD

The investigator reported that the events coronary artery disease and angina unstable were not related to blinded investigational drug, to the device or to the study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that the event coronary artery disease worsened was not related to blinded investigational drug, to the device or to the study conduct.

Study Drug : Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Thyroid nodule	Thyroid mass (Thyroid nodule)	PPD

Case Narrative : Information received on PPD : this P year old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed thyroid nodule [PT: thyroid mass].

The subject's historical medical condition included PPD . The subject's surgical history included PP The subject's current medical condition included dyslipidemia and Type 2 diabetes. No concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of the study visit on PPD .
PPD

The subject's last dose of blinded investigational drug prior to the event was on an unknown date. PPD

The investigator reported that the event thyroid mass was not related to blinded investigational drug or the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
lumbar disc herniation	Intervertebral disc protrusion (Lumbar disc herniation)	PPD (6 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with

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clinically evident cardiovascular disease and developed lumbar disc herniation.

The subject's medical history included PPD. Previous treatment for the condition under study was not reported. Concomitant medications included Aspirin (acetylsalicylic acid) and olmesartan.

On PPD the subject was screened and signed informed consent form. On PPD, the subject was randomized and received the first dose of blinded investigational study drug. Approximately one year and six months later on PPD the subject was hospitalized due to osphyalgia and activity restriction after sprain of two days. On the same day, computerized tomogram (CT) was performed which showed mild bulge of lumbar (L) intervertebral disc of L3-L5. The subject was diagnosed with lumbar disc herniation. The subject received "trophic nerve and strong skeleton". The subject's pain was relieved with unspecified medication and the subject was asked to reduce activity. The outcome of the event lumbar disc herniation was reported as unknown. At the time of this reporting, the subject was still hospitalized. The subject received last dose of blinded investigational study drug prior to the event on PPD. The subject completed the study.

The investigator reported that there was not a reasonable possibility that the event lumbar disc herniation was related to blinded investigational study drug. As reported causality for device was not provided by the investigator.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Intramuscular	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Gastrinoma	Gastrinoma (Gastrinoma)	PPD (20 days)

Case Narrative : Initial Receipt Date =PPD

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This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed a gastrinoma.

The subject's medical history included PPD. Previous and current treatment for condition under study was not reported. Concomitant medication included irbesartan.

The subject received the first dose of blinded investigational study drug on PPD. The subject received last dose of blinded investigational study drug on PPD. On PPD the subject completed the study. PPD

The investigator reported that there was not a reasonable possibility that the event gastrinoma was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug :

Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Intramuscular	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
unstable angina pectoris	Angina unstable (Angina pectoris unstable)	PPD (89 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed unstable angina pectoris [PT: Angina unstable].

The subject's medical condition included Dyslipidaemia, Hypertension, Diabetes, Myocardial Infarction. The subject had intermittent chest pain and oppression in chest for 17 years. Concomitant medications included Aspirin (Acetylsalicylic Acid), Metoprolol (Metoprolol), and Insulin (Insulin).

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The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study on PPD . PPD . The subject's last dose of blinded investigational drug prior to the event was on PPD PPD

The investigator reported that the event Angina unstable was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD e.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Sequelae of cerebral infarction	Cerebral infarction (Cerebral infarction)	PPD (30 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Sequelae of cerebral infarction [PT: Cerebral infarction].

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The subject's historical medical condition included PPD. The subject's current medical condition included Dyslipidemia, Type 2 Diabetes Mellitus, and Hypertension. Concomitant medications included Aspirin (Acetylsalicylic acid), insulin, captopril, and Levamlodipine Besilate (Levamlodipine Besilate).

The subject received the first dose of blinded investigational study drug on PPD. The subject completed the end of study on PPD.
PPD
. The subject's last dose of blinded investigational drug prior to the event was on PPD PPD
.

The investigator reported that the event Cerebral infarction was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Inguinal hernia	Inguinal hernia (Inguinal hernia)	PPD (34 days)

Case Narrative : Initial Receipt Date = PPD.

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed inguinal hernia.

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The subject's medical hisotry included PPD. Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. The subject completed the end of study on PPD.
PPD
The subject received the last dose of blinded investigational study drug prior to the event on PPD

The investigator reported that there was not a reasonable possibility that the event inguinal hernia was related to blinded investigational study drug, to the device, or to the study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Unstable angina	Angina unstable (Unstable angina)	PPD (27 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-Cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed unstable angina.

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The subject's medical history included PPD . No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug was on PPD The investigator reported that the subject completed the end of study visit. PPD

The investigator reported that there was not a reasonable possibility that the event unstable angina was related to blinded investigational study drug or to the device.

Correction dated PPD : The outcome of the event unstable angina was reported as resolved on PPD .

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Pneumonia	Pneumonia (Pneumonia)	PPD --

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed pneumonia [PT: Pneumonia].

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No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD. Approximately 602 days later, on PPD, the subject went to the clinic due to cough, expectoration, and fever. On PPD computerized tomogram (CT) scan showed right lung pneumonia. On PPD the subject was hospitalized. On the same day, the subject's laboratory tests showed C-reactive protein (CRP) 29.36 mg/l, neutrophil percentage 73.3%, and white blood cell (WBC) 7.7 x 10e9/L. During hospitalization, the subject received unspecified antibiotics. Treatment reported after the onset of event included Sulperazone (Cefoperazone Sodium, Sulbactam Sodium). The subject's last dose of blinded investigational study drug prior to the event was on PPD The outcome of the event Pneumonia was reported as Recovering/Resolving. At the time of this report, the subject was still hospitalized. Action taken with the blinded investigational study drug was reported as unknown for the event Pneumonia.

The investigator reported that the event Pneumonia was not related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD On PPD, laboratory tests showed C-reactive protein (CRP) 0.54 mg/l, neutrophil (N) percentage 6%, and white blood cell (WBC) 6.8 x 10e9/L. Treatment reported after the onset of event included cefuroxime and ambroxol. The subject received other unspecified treatment. The outcome of the event pneumonia was reported as resolved on PPD and the subject was discharged from the hospital on the same day.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Cholangitis acute	Cholangitis acute (Cholangitis acute)	PPD (17 days)

Case Narrative : Initial Receipt Date = PPD.

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-Cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed cholangitis acute.

The subject's medical history included PPD Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

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The subject received the first dose of blinded investigational study drug on an unknown date. On PPD the subject was admitted to hospital for myocardial infarction and was treated with coronary stent implantation. During hospitalization, the subject complained of abdominal discomfort which was examined. On PPD , the subject completed end of study. PPD

The subject received the last dose of blinded investigational study drug prior to the event on an unknown date.

The investigator reported that there was not a reasonable possibility that the event cholangitis acute was related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug :

Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Transient ischemic attack	Transient ischaemic attack (Transient ischemic attack)	PPD (90 days)

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Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and had transient ischemic attack.

The subject's medical history included PPD PPD Previous treatment for the condition under study was not reported. Concomitant medications included atorvastatin, Tevanel (risedronate sodium), Texid (tranexamic acid), and telmisartan.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational study drug was on PPD The subject's end of study was done on PPD PPD

The investigator reported that there was not a reasonable possibility that the event transient ischemic attack was related to blinded investigational study drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Worsening of hypertension	Hypertension (Hypertension aggravated)	PPD (29 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and experienced worsening of hypertension.

The subject's medical history included PPD Previous treatment for the condition under study was not provided. Concomitant medication included

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atorvastatin.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of the blinded investigational study drug prior to the event was on PPD . On PPD the subject completed the study (end of study). PPD

The investigator reported that there was not a reasonable possibility that the event worsening of hypertension was related to blinded investigational study drug. For the event worsening of hypertension, as reported causality of device was not provided by the investigator.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that there was not a reasonable possibility that the event worsening of hypertension was related to device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Acute myocard infarction	Acute myocardial infarction (Acute myocardial infarction)	PPD (17 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A

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Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had an Acute myocardial infarction [PT: Acute myocardial infarction] and underwent Coronorography selective [PT: Arteriogram coronary].

The subject's current medical history includes PPD . Concomitant medications included Godasal (Acetylsalicylic Acid, Glycine), Brilique (Ticagrelor), Concor (Bisoprolol Fumarate), Prestarium Neo (Perindopril Arginine), Controloc (Pantoprazole), Finpros (Finasteride), Capistan (Serenoa Repens), Preductal (Trimetazidine Hydrochloride), Sortis (Atorvastatin Calcium), Lipanthyl (Fenofibrate), Metformin (Metformin), and Agen (Amlodipine Besilate).

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug was on PPD . On PPD , the subject completed study. PPD

The investigator reported that the events Arteriogram coronary and Acute myocardial infarction were not related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Stroke	Cerebrovascular accident (Stroke)	PPD (13 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular

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Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had Stroke [PT: Cerebrovascular accident].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject completed end of study. P The subject's last dose of blinded investigational drug prior to the event was on PPD PPD .

The investigator reported that the event Cerebrovascular accident was not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

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PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Myocardie stenosis	Coronary artery stenosis (Coronary artery stenosis)	PPD ---
cardiac arrest	Cardiac arrest (Cardiac arrest)	PPD (13959 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed "Myocardie" stenosis [PT: Coronary artery stenosis] and life-threatening cardiac arrest [PT: Cardiac arrest].

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The subject's medical history includes PPD
PPD
PPD The subject's historical drug included PPD Concomitant medications included Clopidogrel (Clopidogrel), Eltroxin (Levothyroxine Sodium), Lercanidipine (Lercanidipine), Centyl K (Bendroflumethiazide, Potassium Chloride).

The subject received the first dose of blinded investigational study drug on PPD . Approximately 644 days later, on PPD

The investigator reported that the events Coronary artery stenosis and life-threatening Cardiac arrest were not related to blinded investigational drug or study device.

ADDITIONAL INFORMATION RECEIVED ON PPD : As per investigator, the subject completed the end of study (EOS) on PPD and the reported events happened after EOS visit.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
increasing serum creatinin	Blood creatinine increased (Increased serum creatinine)	PPD (34 days)

Case Narrative : Initial Receipt Date = PPD

This P year old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed increasing serum

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creatinine [PT: Blood creatinine increased].

The subject's medical history included PPD PPD Concomitant medications included Atorvastatin (Atorvastatin), Paracetamol (Paracetamol), Tazocin (Piperacillin Sodium, Tazobactam Sodium), Furix (Furosemide), Metoprolol Succinate (Metoprolol Succinate), Glimepiride (Glimepiride), Trimopan (Trimethoprim), Innohep (Tinzaparin Sodium), Pivmecillinam (Pivmecillinam), Pondocillin (Pivampicillin), Azithromycin (Azithromycin), Nitrofurantoin (Nitrofurantoin), Digoxin (Digoxin), Ciprofloxacin (Ciprofloxacin), Alfacalcidol (Alfacalcidol), Clopidogrel (Clopidogrel), Hjertemagnyl (Acetylsalicylic Acid), Felodipin (Felodipine), Citalopram (Citalopram), Allopurinol (Allopurinol), Losartan (Losartan), Cetirizine Hydrochloride (Cetirizine Hydrochloride), Movicol (Macrogol 3350, Potassium Chloride, Sodium Bicarbonate, Sodium Chloride), Kaleorid (Potassium Chloride), Ferrous Sulphate (Ferrous Sulfate), Unikalk Forte (Calcium, Colecalciferol), and Marevan (Warfarin Sodium).

The subject received the first dose of blinded investigational study drug on PPD In PPD to PPD the subject had left side hydronephrosis (reported separately as an SAE). The subject's last dose of blinded investigational drug prior to the event was on PPD Two weeks later on PPD, the subject completed the end of study visit. PPD

The investigator reported that the event Blood creatinine increased was not related to blinded investigational drug or to the device.

Version created in error on PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Revascularisation	Coronary revascularisation (Coronary revascularisation)	PPD (11 days)
Unstable angina	Angina unstable (Unstable angina)	PPD ---

Case Narrative : Initial Receipt Date = PPD

This P years old, PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Unstable

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angina [PT: Angina unstable].

The subject's historical medical condition included PPD The subject's current medical condition included Dyslipidaemia. The subject's surgical history included PPD Concomitant medications included Atorvastatin (Atorvastatin), Oxez (Formoterol Fumarate), Hjertemagnyl (Acetylsalicylic Acid), Bricanyl Turbuhaler (Terbutaline Sulfate), Metoprololsuccinat Hexal (Metoprolol Succinate), Spirocort (Budesonide), Berodual (Fenoterol Hydrobromide, Ipratropium Bromide), Kaleorid (Potassium Chloride), Pamol (Paracetamol), "Furosemid Orifarm", and Clopidogrel (Clopidogrel).

The subject received the first dose of blinded investigational study drug on PPD . On PPD and PPD , the subject experienced unstable angina which were followed with PCI procedure. On PPD , the subject experienced Unstable angina and was hospitalized. On PPD coronary angiography (CAG) was performed which showed a new ostial circumflex (Cx) stenosis as well as ostial left anterior descending artery (LAD) instent re-stenosis. The latter involved the distal part of the main branch. Due to CAG result, coronary artery bypass graft (CABG) surgery was planned on PPD The subject had normal ejection fraction (60 %) and no significant valve diseases were noted. The subject's present treatment was continued except Clopidogrel (Clopidogrel). Clopidogrel (Clopidogrel) had been paused until the operation. The subject was stayed in hospital until operation. On PPD the CABG went well with left internal mammary artery (LIMA) to LAD and vein to ramus descendens posterior artery (RDP), obtuse marginal artery (OM), and "IM". The subject's enzymes creatinine kinase MB maximum 20, which was fully in accordance with the performed surgical intervention. The subject developed pneumonia immediately postoperatively and therefore admitted to intensive care for several days. The subject recovered slowly and was discharged to subject's own hospital department. The subject had only slightly elevated blood sugars and about a year ago, he had glycosylated haemoglobin (HbA1c) with a value of 0. Thus, the subject had no signs of diabetes prior to this procedure and it was interpreted as surgical stress with add-on pneumonia. The subject was stayed in hospital for a couple of more days because of pneumonia after operation. Treatment reported after the onset of event included Heparin (Heparin), Cardioplegia (Magnesium Chloride, Potassium Chloride, Procaine Hydrochloride), and Protamine (Protamine). No blood transfusion was performed during this admission. The outcome of the event Angina unstable was reported as Recovered/Resolved. The event Angina unstable was resolved on PPD . On the same day, the subject was discharged in well being for the usual rehabilitation at home. The subject was suggested to get another check-up with general physician when after the removal of sutures on day seven to ten. The subject was informed to follow up after a month postoperative control at cardiology department. On PPD the subject received last dose of blinded investigational study drug. On PPD end of study visit was performed.

The investigator reported that the event Angina unstable was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that the event revascularisation was not related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
worsening claudication	Intermittent claudication (Claudication)	PPD (13 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and underwent femoropopliteal artery bypass right leg.

The subject's medical history included PPD
PPD

The subject received the first dose of blinded investigational study drug on PPD . The subject received the last dose of blinded investigational study drug prior to the event on PPD The study was ended on PPD . Over the last year, the subject suffered from pain in both legs at physical activities and at night. In PPD "gible pressure" was 500 mmHg right side and "A Bi" was 33 % right side. On an unknown date, the subject was diagnosed with arterial insufficiency "stadium III". PPD

The investigator reported that there was not a reasonable possibility that the event femoropopliteal artery bypass right leg was related to blinded investigational study drug and to device.

ADDITIONAL INFORMATION RECEIVED ON PPD Previously reported event term femoropopliteal artery bypass right leg was updated to worsening claudication. Previously reported "gible pressure" was ankle pressure and "A Bi" was ankle brachial index test.

The investigator reported that there was not a reasonable possibility that the event worsening claudication was related to blinded investigational study drug and to device.

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
hip discomfort	Musculoskeletal discomfort (Hip discomfort)	PPD (26 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD female subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and underwent a hip replacement.

The subject's medical history included PPD . Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . Approximately two years and five months later on PPD , the subject experienced hip discomfort. PPD

possibility that the event hip replacement was related to blinded investigational drug and study device.

ADDITIONAL INFORMATION RECEIVED ON PPD . The subject's last dose of blinded investigational study drug was on PPD The subject's end of study visit was performed on PPD

The investigator reported that there was not a reasonable possibility that the event hip discomfort was related to blinded investigational drug and study device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The investigator confirmed the start date of event as PPD .

Study Drug : Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Stroke	Cerebrovascular accident (Stroke)	PPD (128 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, and died due to Stroke [PT: Cerebrovascular accident].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD The subject's last dose of blinded investigational drug was on PPD On PPD the subject was hospitalized due to benign meningioma. During hospitalization on PPD , the subject had stroke and was "never really awake since this event". On PPD end of study visit was performed. PPD

The investigator reported that the fatal event Cerebrovascular accident was not related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Atrial fibrillation	Atrial fibrillation (Atrial fibrillation)	PPD (9 days)

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Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed atrial fibrillation.

The subject's medical history included PPD Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on unknown date. On PPD at 10 am, the subject was hospitalized due to chest pain. Electrocardiogram (ECG) showed atrial fibrillation. Laboratory tests included troponin T (TNT) 1510 ng/L and creatine phosphokinase (CK) 308 U/L. The subject received Eliquis (apixaban) as treatment medication. On PPD the subject's troponin T was 4270 ng/L and CK was 1150 U/L. Spontaneous conversion to sinus rhythm was noted and the chest pain disappeared. The outcome of the event atrial fibrillation was reported as resolved on PPD and on the same day, the subject was discharged from the hospital with Selozok (metoprolol succinate). The subject received the last dose of blinded investigational study drug prior to the event on an unknown date. Action taken with blinded investigational study drug was unknown.

The investigator reported that there was not a reasonable possibility that the event atrial fibrillation was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject received first dose of blinded investigational study drug on PPD The subject did not have myocardial infarction (MI). As per investigator, final diagnosis was atrial fibrillation. The subject received last dose of blinded investigational study drug on PPD . On the same day, the subject completed the study.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Angina pectoris	Angina pectoris (Angina pectoris)	PPD (17 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, female subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically

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evident cardiovascular disease and developed angina pectoris.

The subject's medical history included PPD PPD Previous treatment for the condition under the study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. The subject received last dose of blinded investigational study drug prior to the event on an unknown date. The subject completed end of study on PPD PPD

The investigator reported that there was not a reasonable possibility that the event angina pectoris was related to blinded investigational study drug, or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject received last dose of blinded investigational study drug prior to the event on PPD .

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
EROSIVE GASTRITIS	Gastritis erosive (Gastritis erosive)	PPD (30 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, and experienced Weight loss [PT: Weight decreased].

The subject's current medical condition included Dyslipidemia. The subject had no relevant history for weight loss. Concomitant medications included

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Metolar (Metoprolol Tartrate), Agen (Amlodipine Besilate), Micardis (Telmisartan), Pradaxa (Dabigatran Etexilate Mesilate), and "coxardio".

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study on PPD PPD

The investigator reported that the event Weight decreased was not related to blinded investigational drug or to study device. No concomitant medications were considered as co-suspect drug.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that the event erosive gastritis was not related to blinded investigational drug or to device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Pneumonia	Pneumonia (Pneumonia)	PPD (20 days)

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Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed tuberculosis.

The subject's medical history included PPD. Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on unknown date. The subject completed the end of study visit on PPD. PPD. The subject received the last dose of blinded investigational study drug prior to the event on an unknown date.

The investigator reported that there was not a reasonable possibility that the event tuberculosis was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD: The investigator reported that the subject received the first dose of blinded investigational study drug on PPD The subject received the last dose of blinded investigational study drug prior to end of study on PPD The investigator did not know the resolution date of the event tuberculosis.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator reported that there was not a reasonable possibility that the event pneumonia was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Worsening of coronary lesions	Coronary artery disease (Coronary artery disease aggravated)	PPD (13 days)

Case Narrative : Initial Receipt Date = PPD (

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, underwent Coronary revascularization [PT: Coronary revascularization].

The subject's historical medical condition included PPD PPD. The subject's current medical condition included dyslipidemia, hypertension arterial. Concomitant medications included Plavix (Clopidogrel Bisulfate), Ramipril (Ramipril), Tahor (Atorvastatin Calcium), Esidrex (Hydrochlorothiazide) and "Tement". No relevant co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug was on an unknown date. On PPD , the subject was hospitalized due to unspecified reason. On PPD , the subject underwent end of study visit. PPD

The investigator reported that the event Coronary revascularization was not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

The investigator reported that the event worsening of coronary lesions was not related to blinded investigational drug or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Myocardial infarct	Myocardial infarction (Myocardial infarct)	PPD (14 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular

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Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease And developed Myocardial infarct [PT: Myocardial infarction].

The subject's historical medical condition included PPD PPD PPD The subject's current medical condition included Dyslipidemia, PPD and Reopro Allergy. Surgical procedure included Stent, Angioplasty Of The Distal Right Coronary, Percutaneous Coronary Intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA) and Complete Revascularization. Risk factors included former smoker, heredity, and hypercholesterolemia. Concomitant medications included Atorvastatin (Atorvastatin), Candesartan (Candesartan), Conebilox (Hydrochlorothiazide, Nebivolol Hydrochloride), and Pantoprazole (Pantoprazole).

The subject received the first dose of blinded investigational study drug on PPD. The subject's last dose of blinded investigational drug on PPD On PPD, the subject's end of study visit was performed. PPD

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PPD

The investigator reported that the event Myocardial infarction was not related to blinded investigational drug and to study device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Tight stenosis > 75% of right external iliac artery calcified atheromatous plaque	Peripheral artery stenosis (iliac artery stenosis)	PPD ---

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed tight stenosis > 75% of right external iliac artery calcified atheromatous plaque.

The subject's medical condition included PPD Previous treatment for the condition under study was not reported. Concomitant medications included Crestor (rosuvastatin calcium), Kardegic (acetylsalicylate lysine), and Ezetrol (ezetimibe).

The subject received the first dose of blinded investigational study drug on unknown date. On PPD the subject's symptoms started with right leg pain while walking. On PPD angioscan of the abdominal aorta and lower limb were done which revealed tight stenosis greater than 75 % of right external iliac artery on calcified atheromatous plaque. On PPD the subject was hospitalized and underwent stent placement on PPD . No complications were noted in early post surgical period. The outcome of the event tight stenosis > 75% of right external iliac artery calcified atheromatous plaque was reported as resolved on PPD and the subject was discharged from the hospital on the same day. The subject was prescribed with

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Plavix (clopidogrel bisulfate) for three months. The subject received the last dose of blinded investigational study drug prior to the event on PPD . Blinded investigational study drug was continued. The subject then completed end of study on PPD

The investigator reported that there was not a reasonable possibility that the event tight stenosis > 75% of right external iliac artery calcified atheromatous plaque was related to blinded investigational study drug or to the device. None of the concomitant medications were considered as co-suspect.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Percutaneous coronary intervention	Percutaneous coronary intervention (Percutaneous coronary intervention)	PPD (6 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and underwent percutaneous coronary intervention.

The subject's medical history included PPD . Previous treatment for the condition under study was not reported. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . Approximately one year, 11 months, and three weeks later on PPD the subject was hospitalized for a planned coronarography of which results were not provided. On the same day, the subject underwent percutaneous coronary intervention. No treatment information was provided. The outcome of the event percutaneous coronary intervention was reported as ongoing. The subject's last dose of blinded investigational study drug prior to the event was on PPD On an unknown date, study drug was discontinued.

For the event percutaneous coronary intervention, as reported causality for device was not provided by the investigator. The investigator reported that there was not a reasonable possibility that the event percutaneous coronary intervention was related to blinded investigational study drug.

ADDITIONAL INFORMATION RECEIVED ON PPD

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Depression	Depression (Depression)	PPD (28 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had Depression [PT: Depression].

No historical medical condition was reported. The subject's current medical condition included dyslipidemia and depression. Concomitant medications included Valium (Diazepam) and Depakote (Valproate Semisodium).

The subject received the first dose of blinded investigational study drug on PPD. The subject's last dose of blinded investigational drug prior to the event was on PPD. On PPD, the subject completed end of study (EOS) visit. PPD

The investigator reported that the event Depression was not related to blinded investigational drug and device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
hospitalization for coronarography	Arteriogram coronary (Coronary angiogram)	PPD (15 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and underwent "hospitalization for coronarography".

The subject's medical history included PPD . Previous treatment for the condition under study was not reported. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD The subject completed the end of study visit on PPD . PP D The subject received the last dose of blinded investigational study drug prior to the event on PPD

The investigator reported that there was not a reasonable possibility that the event "hospitalization for coronarography" was related to blinded investigational study drug, to the device, or to the study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject completed the study and the investigator confirmed that the event occurred after end of study.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Ventricular tachycardia	Ventricular tachycardia (Ventricular tachycardia)	PPD (106 days)

Case Narrative : Information received on PPD , this P years old male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-

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Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed fatal event ventricular tachycardia [PT: ventricular tachycardia].

No historical medical condition was reported. The subject's current medical condition included dyslipidaemia. No concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. The subject completed End of Study on PPD . P . The subject's last dose of blinded investigational study drug prior to the event was on an unknown date PPD

The investigator reported that the fatal event ventricular tachycardia was not related to blinded investigational study drug and device.

ADDITIONAL INFORMATION RECEIVED ON PPD : PPD

The subject did not have history of valvular disease. The subject received the first dose of blinded investigational study drug on PPD (previously reported as unknown date). Since PPD the subject developed heart failure. In PPD the subject underwent CABG. On admission, the subject had Glasgow coma scale 3/15; temperature 34.8 degree Celsius; oxygen saturation (SPO2) 92 %, and fraction of inspired oxygen (FiO2) 100 %. The subject's laboratory tests included pH 7.16, partial carbon dioxide (PaCO2) 48.4 mm Hg, partial oxygen (PaO2) 71.3 mm Hg, troponin 0.52 ug/ml, leukocyte 17000/mm3, hemoglobin 15.3 g/dL, platelet 222000/mm3, sodium (Na) 136 mmol/l, potassium (K) 2.07 mmol/l, protein 66 g/l, creatinine 175 umol/l, urea 9.9 mmol/l, creatine phosphokinase (CPK) 515 U/l, aspartate aminotransferase (ASAT) 213 UI/l, alanine aminotransferase (ALAT) 178 UI/l, and bilirubin 22 umol/l. The investigator confirmed that the subject died on PPD and no autopsy was performed. Additionally, the investigator stated that the subject had no ventricular tachycardia before the event. The subject's last dose of blinded investigational study drug prior to the event was on PPD (previously reported as unknown date).

ADDITIONAL INFORMATION RECEIVED ON PPD

PPD

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PPD

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PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Cardiac chest pain	Angina pectoris (Chest pain - cardiac)	PPD (19 days)
Stenosis in RCA	Coronary artery stenosis (Right coronary artery stenosis)	PPD (33 days)
Worsening of heart failure	Cardiac failure (Heart failure)	PPD (30 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed thoracic pain.

The subject's medical history included PPD PPD . Previous treatment for the condition under study was not reported. Concomitant medications included atorvastatin, ramipril, bisoprolol, and Aspirine (acetylsalicylic acid).

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study on PPD . PP

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PPD [redacted]. The subject received the last dose of blinded investigational study drug prior to the event on PPD

The investigator reported that there was not a reasonable possibility that the event thoracic pain was related to blinded investigational drug and study device. No concomitant medications were considered as co-suspect.

ADDITIONAL INFORMATION RECEIVED ON PPD [redacted]

The investigator reported that there was not a reasonable possibility that the events cardiac chest pain, stenosis in RCA, and worsening of heart failure was related to blinded investigational drug and study device. No concomitant medications were considered as co-suspect.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
non-cardiac chest pain	Non-cardiac chest pain (Non-cardiac chest pain)	PPD (41 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had Hospitalization [PT:

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Hospitalisation].

The subject's historical medical condition included PPD The subject's current medical condition included Dyslipidemia, Coronary artery disease (CAD), Hypertension, and Hypercholesterolemia. Concomitant medications included Atorvastatin (Atorvastatin), Aspirine (Acetylsalicylic Acid), Bisoprolol (Bisoprolol), and Ramipril (Ramipril).

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study on PPD . PPD The subject's last dose of blinded investigational drug prior to the event was unknown. PPD

The investigator reported that the event Hospitalisation was not related to blinded investigational drug and to the device. No concomitant medications were considered as co-suspect.

ADDITIONAL INFORMATION RECEIVED ON PPD . The subject's last dose of blinded investigational drug prior to the event was on PPD The subject completed the study. End of the study (EOS) visit was on PPD

The investigator reported that the event non-cardiac chest pain was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The outcome of the event non-cardiac chest pain was reported as resolved on PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Coronary revascularisation because of worsening cardial	Coronary artery disease (Coronary artery disease aggravated)	PPD (34 days)

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
arterial disease		

Case Narrative : Initial Receipt Date = PPD

This P years old male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed Coronary revascularisation [PT: Coronary revascularisation].

The subject's medical history included PPD . Concomitant medications included Ass (Acetylsalicylic Acid), Amlodipin (Amlodipine), Metoprolol (Metoprolol), Enalapril (Enalapril Maleate), Torsemide (Torasemide).

The subject received the first dose of blinded investigational study drug on unknown date. The subject was hospitalized from PPD to PPD for worsening coronary artery disease (reported serious adverse event as per investigator) and coronary artery bypass graft (CABG) was planned. On PPD , the subject completed the end of study. PPD

The subject's last dose of blinded investigational drug prior to the event was on PPD PPD

The investigator reported that the event Coronary revascularisation was not related to blinded investigational drug or study device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The subject received the first dose of blinded investigational study drug on PPD PPD .

The investigator reported that the event coronary revascularisation because of worsening "cardial" arterial disease was not related to blinded investigational drug or study device.

Version created in error on PPD .

Study Drug :

Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Acute on chronic renal failure	Acute kidney injury (Acute on chronic renal failure)	PPD (19 days)
Campylobacter enteritis	Campylobacter gastroenteritis (Campylobacter gastroenteritis)	PPD (14 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed acute renal failure [PT: Acute kidney injury] and Campylobacter enteritis [PT: Campylobacter gastroenteritis].

The subject's historical medical condition included PPD . The subject's current medical condition included Dyslipidemia, Hypertension, Diabetes Type 2, Sleeping Apnea, Chronic Renal Insufficiency, Lumbar Spine Degeneration, Fat Metabolism Disorder, Adipositas, Renal Anemia, Gonarthrosis Both Sides, Cardiac Insufficiency, Aortic Valve Stenosis, Ventral Valve Stenosis, and "abdomen cover area". The subject's surgical history included PPD . No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on an unknown date. End of study was completed on PPD . P P D

The investigator reported that the event Acute kidney injury and Campylobacter gastroenteritis were not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

ADDITIONAL INFORMATION RECEIVED ON PPD The subject's last dose of blinded investigational study drug was on PPD The subject received "rehydration" after onset of the event.

The investigator reported that the event acute on chronic kidney failure was not related to blinded investigational drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Decompensated heart failure	Cardiac failure (Decompensated heart failure)	PPD (67 days)

Case Narrative : Information received on PPD This PPD male subject (number: PPD) approximately P years of age, was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed decompensated heart failure [PT: cardiac failure].

The subject's historical medical condition included PPD The subject's surgical history included PPD PPD . The subject's current medical condition included dyslipidemia, coronary heart disease, chronic heart failure, atrial fibrillation, arterial hypertension, hypercholesterolemia, and chronic anemia. The subject's concomitant medications included Xipamid (xipamide), Enalapril (enalapril), Bisoprolol (bisoprolol), Clopidogrel (clopidogrel), and Phenprocoumon (phenprocoumon). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . On an unknown date in PPD , the subject was implanted with

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pacemaker. On PPD , end of study visit occurred . PPD The subject's last dose of blinded investigational drug prior to the event was on PPD . The outcome of the event cardiac failure was reported as not resolved.

The investigator reported that the event cardiac failure was not related to blinded investigational drug or device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The outcome of the event decompensated heart failure was reported as resolved on PPD .

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Peripheral arterial disease, worsened	Peripheral arterial occlusive disease (Peripheral arterial disease)	PPD (104 days)

Case Narrative : Information received on PPD this P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed peripheral arterial disease, worsened [PT: peripheral arterial occlusive disease].

The subject's historical medical condition included PPD . The subject's current medical condition included dyslipidaemia, peripheral arterial disease, varicosis, and hypercholesterolemia. The subject's concomitant medications included Clopidogrel (clopidogrel) and ASA (acetylsalicylic acid). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug was on PPD . On PPD end of study visit was performed.
PPD

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PPD

The investigator reported that the event peripheral arterial occlusive disease was not related to blinded investigational drug or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Fractured patella right	Patella fracture (Patella fracture)	PPD (13 days)

Case Narrative : Initial Receipt Date = PPD

This P years old, PPD male was participating in a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed fractured patella right [PT: Patella fracture].

The subject's medical history included PPD Previous treatment for the condition under study was not reported. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . Approximately one year, seven months, and one week later on PPD the subject completed End of Study. PPD

. The subject's last dose of blinded investigational drug prior to the event was on PPD

The investigator reported that the event Patella fracture was not related to blinded investigational drug, to the device, and to the study conduct.

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ADDITIONAL INFORMATION RECEIVED O PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Rotator cuff tear	Rotator cuff syndrome (Rotator cuff tear)	PPD (1 day)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Shoulder pain [PT: Musculoskeletal pain].

No historical medical condition was reported. The subject's current medical condition included Dyslipidaemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . Approximately one year and two weeks later, on PPD , the subject developed PPD On PPD , the subject underwent end of study visit. PPD

The subject's last dose of blinded investigational study drug prior to the event was on PPD PPD

The investigator reported that the event Musculoskeletal pain was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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The investigator reported that the event rotator cuff tear was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject ID was corrected from PPD to PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Seizure	Seizure (Seizure)	PPD (51 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and experienced a seizure.

The subject's medical condition included PPD. Previous treatment for the condition under study was not provided. Concomitant medications included ASS (acetylsalicylic acid) and clopidogrel.

The subject received the first dose of blinded investigational study drug on PPD The subject underwent percutaneous coronary intervention (PCI) with stenting in PPD due to coronary heart disease. Five months later in PPD the subject underwent peripheral revascularization on right side. On PPD the subject completed the end of study. PPD

The subject received the last dose of blinded investigational study drug prior to the event on PPD

The investigator reported that there was not a reasonable possibility that the event stroke was related to blinded investigational study drug or to the device. No concomitant medications were considered as co-suspect.

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ADDITIONAL INFORMATION RECEIVED PPD

The subject did not have a history of congenital brain malformation and there was no family history of epilepsy.

PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Unstable angina/hospitalization	Angina unstable (Unstable angina)	PPD (40 days)

Case Narrative : Initial Receipt Date = PPD.

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed life-threatening unstable angina/hospitalization.

The subject's medical history included PPD PPD Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. Approximately one year, four months and 2 weeks later on PPD, the subject completed End of Study. PPD

The subject's last dose of blinded investigational study drug prior to the event was on PPD

The investigator reported that there was not a reasonable possibility that the life-threatening event unstable angina/hospitalization was related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
chest dyscomfort and effort dyspnea (not typical anginal pain)	Chest discomfort (Chest discomfort)	PPD (26 days)
chest dyscomfort and effort dyspnea (not typical anginal pain)	Dyspnoea exertional (Dyspnea on effort)	PPD (26 days)

Case Narrative : Information received on PPD this P years old PPD female subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and underwent percutaneous coronary intervention [PT: percutaneous coronary intervention].

The subject's historical medical condition included PPD . The subject's current medical condition included dyslipidemia and ischemic heart disease. The subject's concomitant medications included Rosuvastatin (rosuvastatin). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject received the last dose of blinded investigational study drug on PPD . The subject had end of study (EOS) visit on PPD . PPD

The investigator reported that the event percutaneous coronary intervention was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD PPD The investigator reported that the blinded investigational study drug was administered subcutaneously. The subject received the last dose of blinded investigational study drug on PPD (previously reported as PPD).

The investigator reported that the events chest dyscomfort and effort dyspnea (not typical anginal pain) were not related to blinded investigational drug and to the device.

CORRECTION DATED ON PPD : This version was created to correct the subject ID from PPD to PPD

Study Drug :

Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Uncontrolled hypertension	Hypertension (Uncontrolled hypertension)	PPD (81 days)

Case Narrative : Initial Receipt Date = PPD

This P years old, female subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, and developed Uncontrolled hypertension [PT: Hypertension].

The subject's historical medical condition included PPD The subject's current medical condition included Dyslipidemia, and Hypertension. Surgical history PPD . Concomitant medications included Atorvastatin (Atorvastatin), Sotalol (Sotalol), Xarelto (Rivaroxaban), Valsartan (Valsartan).

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD end of study was completed. P P D

The investigator reported that the event Hypertension was not related to blinded investigational drug, or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD
PPD

PPD The subject's last dose of blinded investigational drug prior to the event was on PPD .

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject received first dose of blinded investigational study drug on PPD (day of

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randomization).

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
STROKE	Cerebrovascular accident (Stroke)	PPD (17 days)

Case Narrative : Initial Receipt Date = PPD (

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, and developed STROKE [PT: Cerebrovascular accident].

The subject's historical medical condition included PPD The subject's current medical condition included Dyslipidemia, Paroxysmal Atrial Fibrillation, Stroke, Arterial Hypertension, and Temporary Epilepsy under Treatment. Concomitant medications included Bisoprolol (Bisoprolol), Amlodipine (Amlodipine), Furosemide (Furosemide), Ramipril (Ramipril), Phenobarbital (Phenobarbital), Warfarin (Warfarin), and Atorvastatin (Atorvastatin).

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug prior to the event was on PPD . End of study visit was performed on PPD PPD

The investigator reported that the event Cerebrovascular accident was not related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD .

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
GPC bacteremia	Bacteraemia (Gram-positive bacteraemia)	PPD (36 days)

Case Narrative : Initial Receipt Date = PPD.

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease, and developed GPC (gram positive cocci) bacteremia.

The subject's medical history included PPD No previous and current treatment for the condition under study was provided. No other relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. The subject received the last dose of blinded investigational study drug prior to event on PPD The subject completed the study on PPD PPD

The investigator reported that there was not a reasonable possibility that the event GPC bacteremia was related to blinded investigational study drug or to device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Renal failure chronic aggravated	Chronic kidney disease (Renal failure chronic aggravated)	PPD (30 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, female PPD subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed renal failure chronic aggravated.

The subject's medical history included PPD PPD. Previous treatment for the condition under study was not provided. Concomitant medications included furosemide, rosuvastatin calcium, amlodipine besilate, thiamazole, levothyroxine sodium, voglibose, allopurinol, olmesartan medoxomil, lansoprazole, apixaban and "genetical recombination".

The subject received the first dose of blinded investigational study drug on PPD The subject received the last dose of blinded investigational study drug on PPD On PPD the subject had end of study visit. PPD

The investigator reported that there was not a reasonable possibility that the event renal failure chronic aggravated was related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug :

Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
CEREBRAL HAEMORRHAGE	Cerebral haemorrhage (Cerebral haemorrhage)	PPD ---

Case Narrative : Information received on PPD : This P year old female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed a cerebral haemorrhage [PT: cerebral haemorrhage].

The subject's historical medical condition included PPD. The subject's current medical condition included dyslipidemia, diabetes mellitus Type 2, hypertension and hyperlipidemia. Concomitant medications included Onglyza (saxagliptin hydrochloride), Amaryl (glimepiride), Metgluco (metformin hydrochloride), Azilva (azilsartan), Plavix (clopidogrel bisulfate), Takepron (lansoprazole), and Lipitor (atorvastatin calcium). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. Approximately 1 year 5 months later, on PPD at 20:00, speech and language abnormalities were observed PPD

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PPD

PPD The subject's last dose of blinded investigational drug prior to the event was on PPD. The outcome of the event cerebral haemorrhage was reported as not resolved. Action taken with blinded investigational drug was continued for the event cerebral haemorrhage.

The investigator reported that the event cerebral haemorrhage was not related to blinded investigational drug and device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Dizziness	Dizziness (Dizziness)	PPD (50 days)

Case Narrative : Initial Receipt Date = PPD .

This P years old female subject was participating in an Amgen-sponsored clinical trial, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed dizziness

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. Concomitant medication included Cerocral (Ifenprodil Tartrate).

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject completed the study. P PPD

PPD The subject's last dose of blinded investigational drug was on PPD . PPD

The investigator reported that the event dizziness was not related to blinded investigational drug or to the device.

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ADDITIONAL INFORMATION RECEIVED ON PPD : The subject's gender was corrected from female to male. PPD

Study Drug :

Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Hospitalization for stable angina pectoris	Angina pectoris (Stable angina pectoris)	PPD (20 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD female subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and had hospitalization for stable angina pectoris.

The subject's medical history included PPD Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study visit on PPD .
PPD

The investigator reported that there was not a reasonable possibility that the event hospitalization for stable angina pectoris was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

ADDITIONAL INFORMATION RECEIVED ON PPD : The outcome of the event hospitalization for stable angina pectoris was reported as resolved on PPD .

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Worsening of diabetes mellitus	Diabetes mellitus (Diabetes mellitus aggravated)	PPD (355 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Worsening of diabetes mellitus [PT: Diabetes mellitus].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia and Diabetes Mellitus. Concomitant medications included Metformin (Metformin).

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the end of study on PPD . PPD PPD The subject's last dose of blinded investigational drug prior to the event was on PPD . The outcome of the event Diabetes mellitus was reported as Resolved. The event Diabetes mellitus was resolved on PPD and on the same day, the subject was discharged from the hospital.

The investigator reported that the event Diabetes mellitus was not related to blinded investigational drug and to the device. No relevant co-suspect medications were reported.

ADDITIONAL INFORMATION RECEIVED ON PPD

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PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Respiratory isuficiency syndrome	Respiratory failure (Respiratory insufficiency)	PPD ---

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-Cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed fatal respiratory isuficiency syndrome.

The subject's medical history included PPD . Previous treatment for the condition under study was not reported. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD the subject died due to respiratory insufficiency syndrome as per death certificate found in civil records. No other information were available. The end of study visit was completed on PPD .

The investigator reported that there was not a reasonable possibility that the event fatal respiratory isuficiency syndrome was related to blinded investigational study drug and device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Non-cardiac chest pain	Non-cardiac chest pain (Non-cardiac chest pain)	PPD (42 days)

Case Narrative : Initial Receipt Date = PPD

This PP years old, PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease, experienced chest pain [PT: Chest pain].

No historical medical condition was reported. The subject's current medical condition included dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on an unknown date. On an unknown date, the subject completed the study. On PPD the subject experienced chest pain and was hospitalized on the same day. No treatment information was provided. The subject's last dose of blinded investigational drug was on an unknown date. The outcome of the event chest pain was reported as resolved. The event chest pain was resolved on PPD and the subject was discharged from the hospital on the same day.

The investigator reported that the event chest pain was not related to blinded investigational drug and device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The subject's last dose of blinded investigational drug was on PPD . Blinded investigational study drug was discontinued.

The investigator reported that the event non-cardiac chest pain was not related to blinded investigational drug and device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject received the last dose of blinded investigational study drug prior to the event on PPD (previously reported as PPD). The investigator confirmed that the subject completed the study and end of study visit was performed on PPD .

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Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Sudden cardiac death	Sudden cardiac death (Sudden cardiac death)	PPD ---

Case Narrative : Information received on PPD, this P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had sudden cardiac death [PT: sudden cardiac death].

The subject's historical medical condition included PPD. The subject's surgical history included PPD PPD. The subject's current medical condition included dyslipidaemia and hypertension. The subject's concomitant medications included Atorvastatin (atorvastatin), Ticagrelor (ticagrelor), Bisoprolol (bisoprolol), Perindopril (perindopril), and ASA (acetylsalicylic acid). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD, the subject completed end of study (EOS) visit. PPD The cause of death was reported as sudden cardiac death. No treatment information was received. The subject's last dose of blinded investigational drug prior to the event was on an unknown date.

The investigator reported that the event sudden cardiac death was not related to blinded investigational drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Ischemic stroke	Ischaemic stroke (Ischemic stroke)	PPD (59 days)

Case Narrative : Information received on PPD, this P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with

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Clinically Evident Cardiovascular Disease and developed ischemic stroke [PT: ischaemic stroke].

No historical medical condition was reported. The subject's current medical condition included dyslipidaemia. The subject's concomitant medications included Lecalpin (lercanidipine hydrochloride) and Indix (indapamide).

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD , the subject completed the study. P P D

The investigator reported that the event ischaemic stroke was not related to blinded investigational drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject had aortic and mitral stenosis. The subject's last dose of blinded investigational drug prior to the event was on PPD . On PPD , electrocardiogram (ECG) diagnosed paroxysmal atrial fibrillation vestibular (moderate grade) for the first time. The investigator reported that the pain in the chest which was experienced on an unknown date in PPD was not an adverse event (AE) as it was considered as a symptom of coronary heart disease and did not require hospitalization. PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Death (cause unknown)	Death (Unknown cause of death)	PPD (46 days)

Case Narrative : Information received on PPD, this P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and died (cause unknown) [PT: death].

The subject's historical medical condition included PPD. The subject's current medical condition included dyslipidaemia, carotid artery stenosis, hyperlipidaemia, hypertension, diabetes mellitus, and metabolic syndrome. No concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD. The subject's last dose of blinded investigational drug was on PPD. The subject completed the end of study visit on PPD. PPD

The investigator reported that the event death was not related to blinded investigational drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Acute myocardial infarction	Acute myocardial infarction (Acute myocardial infarction)	PPD ---

Case Narrative : Information received on PPD, this P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed acute myocardial infarction [PT: acute myocardial infarction].

No historical medical condition was reported. The subject's current medical condition included dyslipidaemia. No concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. The subject received last dose of blinded investigational study drug on an unknown date. The subject's end of study visit was performed on PPD. PPD

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PPD

The investigator reported that the event acute myocardial infarction was not related to blinded investigational drug, or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Hypertensive crisis	Hypertensive crisis (Hypertensive crisis)	PPD (98 days)

Case Narrative : Information received on PPD this P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed weakness [PT: asthenia], stomach ache [PT: abdominal pain upper] and severe dizziness [PT: dizziness].

No historical medical condition was reported. The subject's current medical condition included dyslipidemia. No concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. The subject completed end of study visit on PPD . On PPD PPD . The subject's last dose of blinded investigational drug prior to the event was on an unknown date. The outcome of the events dizziness, asthenia, and abdominal pain upper were reported as not resolved.

The investigator reported that the events asthenia, abdominal pain upper, and dizziness were not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

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The investigator reported that the event hypertensive crisis was not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : Additional medical history included PPD . Surgical history included PPD . The subject received the first dose of blinded investigational study drug on PPD (previously reported as PPD PPD The subject's last dose of blinded investigational drug prior to the event was PPD (previously reported as an unknown date).

ADDITIONAL INFORMATION RECEIVED ON PPD : The investigator confirmed that the subject received last dose of blinded investigational drug on PPD .

ADDITIONAL INFORMATION RECEIVED ON PPD The investigator clarified that the subject received the first dose of blinded investigational study drug on PPD , last dose of blinded investigational study drug on PPD and ended the study.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
colon cancer	Colon cancer (Colon cancer)	PPD (13 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing

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the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed colon cancer.

The subject's medical history included PPD. Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD, the subject completed the end of study. PPD

The investigator reported that there was not a reasonable possibility that the event colon cancer was related to blinded investigational drug and study device.

ADDITIONAL INFORMATION RECEIVED ON PPD: The subject did not have any medical history or pre-disposing factors associated with the event. The subject did not have family history of colon cancer. The investigator reported that the the subject did not receive any previous and additional current treatment for the condition under study until now. The subject received the first dose of blinded investigational study drug on PPD. On PPD the subject was diagnosed with anemia. PPD. On an unknown date in PP, thorax and abdominal computed tomography (CT) scan showed lymphatic nodes in right mesenteric. Biopsy showed tubulovillous adenoma associated with high grade dysplasia. TNM staging was not available. The subject did not receive any treatment for the event colon cancer. The subject received the last dose of blinded investigational study drug on PPD.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Acute miocardial infarction	Acute myocardial infarction (Acute myocardial infarction)	PPD (24 days)

Case Narrative : Initial Receipt Date = PPD.

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed acute "miocardial" infarction.

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The subject's medical history included PPD Previous treatment for the condition under study was not provided. Concomitant medications included metoprolol succinate, ramipril, isosorbide mononitrate, atorvastatin, and Aspirin (acetylsalicylic acid).

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational study drug was on PPD . The subject completed end of study visit on PPD PPD

The investigator reported that there was not a reasonable possibility that the event acute "miocardial" infarction was related blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : PPD
PPD
PPD The subject received the last dose of blinded investigational study drug prior to the event on PPD .

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Unstable angina	Angina unstable (Unstable angina)	PPD (34 days)

Case Narrative : Initial Receipt Date = PPD .

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had Unstable angina [PT: Angina unstable].

No historical medical condition was reported. The subject's current medical condition included dyslipidemia, arterial hypertension, and coronary artery disease. Concomitant medications included Atorvastatin (Atorvastatin), Carvedilol (Carvedilol), Cardiomagnyl (Acetylsalicylic Acid, Magnesium Hydroxide).

The subject received the first dose of blinded investigational study drug on PPD . The subject completed the study on PPD . P P D The subject's last dose of blinded investigational drug prior to the event was on PPD . The outcome of the event Angina unstable was reported as Resolved. PPD PPD

The investigator reported that the event Angina unstable was not related to blinded investigational drug or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
acute myocardial infarction	Acute myocardial infarction (Acute myocardial infarction)	PPD (24 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with

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clinically evident cardiovascular disease and developed acute myocardial infarction.

The subject's medical history included PPD
PPD Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject received last dose of blinded investigational study drug on PPD On PPD the subject completed end of study. PPD

The investigator reported that there was not a reasonable possibility that the event acute myocardial infarction was related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Unstable Angina	Angina unstable (Unstable angina)	PPD --

Case Narrative : Initial Receipt Date = PPD

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This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Unstable Angina [PT: Angina unstable].

The subject's historical medical condition included PPD. The subject's current medical condition included Dyslipidemia, Hypertension, and Hyperlipidemia. The subject's surgical procedure included angiogram with Stent placement. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on an unknown date. The subject's last dose of blinded investigational drug on an unknown date. On PPD, the subject's end of study visit was performed. PPD

The investigator reported that the event Angina unstable was not related to blinded investigational drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Atypical chest pain	Chest pain (Chest pain)	PPD (30 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and experienced atypical chest pain.

The subject's medical history included PPD. Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose and last dose of blinded investigational study drug on an unknown date. The subject's end of study visit was performed on PPD. PPD
PPD

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The investigator reported that there was not a reasonable possibility that the event atypical chest pain was related to blinded investigational study drug and to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

The investigator confirmed that there was not a reasonable possibility that the event atypical chest pain was related to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
CAROTID ARTERY STENOSIS	Carotid artery stenosis (Carotid artery stenosis)	PPD ---

Case Narrative : Information received on PPD this P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed carotid artery stenosis [PT: carotid artery stenosis].

The subject's historical medical condition included PPD PPD PPD. The subject's surgical history included PPD PPD. The subject's current medical condition included dyslipidaemia, orthosis, hypertension, and diabetes mellitus. No

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concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD. Approximately 1 year 1 month 1 week later on PPD, the subject developed carotid artery stenosis and diplopia. On PPD, the subject was hospitalized for in patient treatment and after care. On PPD the subject underwent stent implantation for carotid artery stenosis. On PPD the subject was discharged from hospital with an unspecified oral medications. Later, the subject came for the planned follow up. On PPD the subject visited the hospital. The investigator reported that information regarding diet, hospital care, and prescription would be obtained in next visit. The subject's last dose of blinded investigational drug prior to the event was on an unknown date. At the time of this report, the subject's was in good health condition with some of the symptoms. The outcome of the event carotid artery stenosis was reported as resolved. The event carotid artery stenosis was resolved on PPD. The investigator reported that the subject did not have follow up visit for diplopia after PPD On PPD, the subject had end of study visit. Action taken with blinded investigational drug was continued for the event carotid artery stenosis.

The investigator reported that the event carotid artery stenosis was not related to blinded investigational drug and to the device.

The event carotid artery stenosis reported to Amgen by the investigator has been adjudicated and does not meet Amgen's pre-defined criteria for study end point.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
pneumonia	Pneumonia (Pneumonia)	PPD (16 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed pneumonia [PT: Pneumonia].

The subject's medical condition included PPD No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD. Approximately two years and nine months later on PPD,

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the subject completed the end of study. PPD PPD PPD The subject's last dose of blinded investigational drug prior to the event was on PPD . The outcome of the event Pneumonia was reported as Recovered/Resolved. PPD PPD

The investigator reported that the event Pneumonia was not related to blinded investigational drug or study device.

ADDITIONAL INFORMATION RECEIVED ON PPD Previously reported medical history was updated from PPD Additional medical history PPD The investigator reported that the subject did not have history of arterial hypertension (HTA). The investigator confirmed the route of administration of blinded investigational study drug as subcutaneous. The subject did not receive any treatment medications for the event pneumonia.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Descompensated heart failure	Cardiac failure (Decompensated heart failure)	PPD (29 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease, developed "Descompensated heart failure" [PT: Cardiac failure].

No historical medical condition was reported. The subject's current medical condition included dyslipidemia. No relevant concomitant medications were provided. No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject was diagnosed with leukemia. On PPD , the subject completed the study. PPD PPD

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PPD

PPD The subject's last dose of blinded investigational drug prior to the event was on PPD. The outcome of the event cardiac failure was reported as resolved. PPD

The investigator reported that the event cardiac failure was not related to blinded investigational drug or device.

ADDITIONAL INFORMATION RECEIVED ONPPD Additional medical history includedPPD PPD The subject did not have history of stroke, smoking, alcohol use or drug use.
On an unknown date in PP, the subject was diagnosed with hyperuricemia. PPD PPD The investigator considered leukemia as non-serious adverse event with grade 3.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Cardiac Ischemic Event - Myocardial Infarction- STEMI	Acute myocardial infarction (STEMI)	PPD (27 days)

Case Narrative : Initial Receipt Date = PPD

This PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed life-threatening Cardiac Ischemic Event - Myocardial Infarction [PT: Myocardial infarction].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD, the subject had myocardial infarction. It was not ST segment elevation myocardial infarction (STEMI). On the same day, the subject's laboratory tests reveled creatine phosphokinase (CPK) 704 U/L and troponin I 19.50 ng/mL. The subject's last dose of blinded investigational drug prior to the event was on PPD On PPD, the subject completed end of study. PPD

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PPD

The investigator reported that the life-threatening event Myocardial infarction was not related to blinded investigational drug and device.

ADDITIONAL INFORMATION RECEIVED ON PPD : This PPD male subject was P years old (date of birth was updated). Additional medical history included PPD The subject had no past medical history of stroke, cardiac rhythm abnormaiities, diabetes, obesity, smoking or alcohol use. Additional concomitant medications included ramipril, bisoprolol, acetylsalicylic acid, pitavastatin, and pentoxifylline.

The investigator confirmed that the onset date of event was PPD and the subject did not have additional event on PPD . Electrocardiogram (ECG) done on PPD which showed ventricular rate 72 bpm, "PR int 165 ms, QRS dur 97 ms, QT/QTc 370/395 ms, P-R-T axes 41 35 72". The subject's final diagnosis was ST segment elevation myocardial infarction (STEMI). The subject was hospitalized within 24 hours of last ischemic symptoms, and the event was not suspected to be due to stent thrombosis. On the same day, coronary artery stent implantation was performed for the event. The investigator considered the event as immediately life threatening. During hospitalization, laboratory tests included leukocytes 9.76 x 10e3/mm3, lymphocyte 21.0 %, monocyte 6.1 %, segmented 69.6 %, eosinophil 3.0 %, basophil 0.3 %, lymphocyte 2.05 x 10e3/mm3, monocyte 0.60 x 10e3/mm3, segmented 6.79 x 10e3/mm3, eosinophil 0.29 x 10e3/mm3, basophil 0.03 x 10e3/mm3, hemoglobin 10.3 g/dL, hematocrit 33.7 %, mean cell volume (VCM) 77.8 fL, "HCM" 23.7 pg, "CHCM" 30.5 g/dL, "ADH" 17.5 %, platelet 171 x 10e3/mm3, "VPM" 10.1 fL, "plaquetocrit" 0.17 %, International normalized ratio (INR) 1.09, activated partial thromboplastin time (APTT) 34.30 seconds, partial thromboplastin (ratio) 1.06, "CTR TTPA" 30.00 seconds, partial prothrombin time prothrombin activity 88.0 %, prothombin time 12.7 seconds, and prothrombin 11.0 seconds.

ADDITIONAL INFORMATION RECEIVED ON PPD Previously reported event term was updated from Cardiac Ischemic Event - Myocardial Infarction to Cardiac Ischemic Event - Myocardial Infarction- STEMI.

The investigator reported that the life-threatening event Cardiac Ischemic Event - Myocardial Infarction- STEMI was not related to blinded investigational drug and device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Myocardial infarction	Myocardial infarction (Myocardial infarction)	PPD (12 days)

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Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, and experienced Chest pain [PT: Chest pain].

The subject's historical medical condition included PPD. The subject's current medical condition included Dyslipidaemia, and Hypertension. The subject's surgical history included PPD. Concomitant medications included Atorvastatin (Atorvastatin), Tramadol (Tramadol), Valsartan (Valsartan), Hydrochlorothiazide (Hydrochlorothiazide), and Felodipine (Felodipine).

The subject received the first dose of blinded investigational study drug on PPD. The subject received the last dose of blinded investigational study drug on PPD. End of study visit was performed on PPD. PPD

The investigator reported that the event Chest pain was not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD: Previously reported event term chest pain was updated to myocardial infarction. Additional medical history included PPD. Additional concomitant medication included Aspirin (acetylsalicylic acid). P PPD

The investigator reported that the event myocardial infarction was not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Ventricular tachycardia	Ventricular tachycardia (Ventricular tachycardia)	PPD (4 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Ventricular tachycardia [PT: Ventricular tachycardia].

The subject's historical medical condition included PPD. The subject's current medical condition included Dyslipidaemia and Heart Failure. Surgical procedure PPD). Concomitant medications included Atorvastatin (Atorvastatin), Trombyl (Acetylsalicylic Acid), Spironolactone (Spironolactone), Bisoprolol (Bisoprolol) and Zestril (Lisinopril).

The subject received the first dose of blinded investigational study drug on PPD. Approximately 2 years, 3 months and 1 week later on PPD the subject was hospitalized. On the same day, the subject underwent implantable defibrillator insertion (ICD) and the subject was diagnosed with Ventricular tachycardia. The subject did not have any other symptoms. The subject underwent antitachycardia pacing (ATP) 3 times and converted to sinus rhythm. The investigator reported that there was no other underlying cause noted except heart failure. "UCG" showed ejection fraction (EF) 30 %. The subject's N-terminal prohormone brain natriuretic peptide (Pro BNP) was 527 (unit not provided). The subject's Bisoprolol dose was increased to 5 mg. The subject's last dose of blinded investigational study drug was on PPD. The outcome of the event Ventricular tachycardia was reported as Resolved. The event Ventricular tachycardia was resolved on PPD and the subject was discharged from the hospital on the same day. On PPD the subject completed the study.

The investigator reported that the event Ventricular tachycardia was not related to blinded investigational study drug, to the device or to study conduct.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
CARDIAC CHEST PAIN	Angina pectoris (Chest pain - cardiac)	PPD (15 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing

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the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and experienced cardiac chest pain.

The subject's medical history included PPD
Previous and current treatment for the condition under study included atorvastatin. Concomitant medications included Insulatard (insulin human injection, isophane), metformin, acetylsalicylic acid, Furix (furosemide), enalapril, citalopram, and "sclobea zoc".

The subject received the first dose of blinded investigational study drug on PPD . Approximately two years, five months, and three weeks later on PPD the subject completed end of study. PPD
. The subject's last dose of blinded investigational study drug prior to the event was on PPD .

The investigator reported that there was not a reasonable possibility that the event cardiac chest pain, was related to blinded investigational study drug or device.

ADDITIONAL INFORMATION RECEIVED ON PPD
PPD Additional concomitant medications included Trombyl (acetylsalicylic acid) and Seloken zoc (metoprolol succinate). Previously reported treatment medications included omeprazole and clopidogrel updated as concomitant medications.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	140 mg, q2wk	Subcutaneous	q2wk	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Acidosis	Acidosis (Acidosis)	PPD (18 days)
HYPOGLYCEMIA	Hypoglycaemia (Hypoglycemia)	PPD (18 days)

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Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and had hypoglycemia and acidosis.

The subject's medical history included PPD
PPD
PPD The subject did not any significant family history. No previous treatment for the condition under study and concomitant medications were reported.

On PPD the subject was hospitalized. The subject had old lacunar infarction, cervical spine spondylosis with radiculopathy, diabetic (DM) polyneuropathy, and diabetes mellitus with poor control. The subject received the first dose of blinded investigational study drug on an unknown date. On PPD , the subject's glycosylated haemoglobin (HbA1c) was 9.2 %. On PPD the subject was hospitalized. The subject had type 2 diabetes mellitus poor control, essential hypertension, and hyperlipidemia. On PPD the subject was hospitalized. The subject had acute decompensated heart failure with pulmonary edema, bilateral pleural effusion, nephrotic syndrome, hypertension with poor control, and hyperlipidemia. On PPD the subject was hospitalized. The subject had sepsis, hyperosmolar hyperglycemic state (HHS), hyponatremia, metabolic encephalopathy, duodenal ulcer (DU) hiatal hernia, and gastric ulcer (GU), CHF III (hypertension (HTN), hypertensive cardiovascular disease (HCVD), and arterio sclerotic heart disease (ASHD)), diabetes mellitus poor control, chronic liver disease, and nephrotic syndrome. On PPD , the subject was hospitalized. The subject had type 2 diabetes mellitus with poor control, hypoglycemia, and anemia cause undetermined. On PPD , the subject's HbA1c was 14 %. End of study visit was completed on PPD

PPD

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PPD

The investigator reported that there was not a reasonable possibility that the events hypoglycemia and acidosis were related to blinded investigational study drug and to the study device or to study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD The subject received the last dose of blinded investigational study drug on PPD (study ended). PPD
PP

ADDITIONAL INFORMATION RECEIVED ON PPD The subject received the first dose of blinded investigational study drug on PPD . The outcome of the event acidosis was reported as resolved on PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
DEATH	Death (Death)	PPD (36 days)

Case Narrative : Information received on PPD , this P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease.

The subject's historical medical condition included PPD The subject's surgical history included PPD
PPD

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PPD
PPD The subject's current medical condition included dyslipidemia, hypertensive cardiovascular disease (HCVD) / hypertensive heart disease, hyperlipidemia, and hypertensive heart disease without heart failure. The subject's concomitant medications included Rytmonorm (propafenone hydrochloride), Olmetec (olmesartan medoxomil), Tenormin (atenolol), Bokey (acetylsalicylic acid), Lipitor (atorvastatin calcium), and Magnesium Oxide (magnesium oxide). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on an unknown date. On PPD , the subject experienced paroxysmal attack. On an unknown date, urine test was performed which showed pyuria. The subject had acute inferior non-Q myocardial infarction (MI) and ventricular fibrillation (VF) on "last week". The subject also had chronic hypercholesterolaemia. On PPD , the subject completed end of study. PPD . The subject's last dose of blinded investigational drug prior to the event was on PPD .

The investigator reported that there was not a reasonable possibility that the event "death" was related to blinded investigational study drug and to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Worsening Heart failure	Cardiac failure (Heart failure)	PPD (1 day)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD female subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed worsening heart failure.

The subject's medical history included PPD
PPD . Previous and current treatment for the condition under study was not provided. Concomitant medication included furosemide.

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The subject received the first dose of blinded investigational study drug on PPD . PPD

he subject's last dose of the blinded investigational study drug prior to the event was on PPD . At the time of this report, the subject was still hospitalized. Blinded investigational study drug was discontinued.

The investigator reported that there was not a reasonable possibility that the event worsening heart failure was related to blinded investigational study drug, device or to the study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject had no significant family history. PPD PPD

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PPD

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PPD

ADDITIONAL INFORMATION RECEIVED ON PPD The investigator reported that the subject had medical history of PPD PPD Hence, gastroesophageal reflux disease, esophagitis, and hypertension could not be considered as serious adverse events (SAE).

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
CABG	Coronary artery bypass (CABG)	PPD (26 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and underwent CABG.

The subject's medical history included PPD PPD. Previous and current treatment for the condition under study was not provided. Concomitant medications included atorvastatin and eplerenone.

The subject received the first dose of blinded investigational study drug on PPD. On PPD, the subject had an angiogram, however the result was not provided. Then the subject was referred for aortic valve replacement (AVR) and possible coronary artery bypass grafting (CABG). The subject's last dose of the blinded investigational study drug was on PPD. On PPD, the subject had end of study visit. PPD

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PPD

The investigator reported that there was not a reasonable possibility that the event CABG was related to blinded investigational study drug, device or to the study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD: At the time of screening, the subject had dry cough and breathlessness which led to the investigations such as chest X-ray (CXR), echocardiogram and coronary angiogram. Due to results of these tests, the subject was referred to mitral valve replacement (MVR) and CABG. The investigator clarified that dry cough and breathlessness would be consider as an adverse events. However; these symptoms were investigated at the time of screening. Hence; they were not considered as serious adverse events.

The investigator reported that there was not a reasonable possibility that the event CABG was related to blinded investigational study drug or device.

ADDITIONAL INFORMATION RECEIVED ON PPD: The investigator stated that the reported event CABG was correct.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
small non-ST elevation MI	Acute myocardial infarction (Non ST segment elevation myocardial infarction)	PPD (7 days)

Case Narrative : Initial Receipt Date = PPD .

This P years old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A

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Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Chest pain [PT: Chest pain].

The subject's historical medical condition included PPD. The subject's current medical condition included Dyslipidaemia, Hypertension, Hypercholesterolemia, Type 2 Diabetes, Acid Reflux, Low Mood/Depression, Diabetic Retinopathy, Erectile Dysfunction, Back Pain, Diabetic Neuropathy, and Memory Loss. The subject had Allergy To Penicillin (Vomiting). Historical procedures included PPD PPD. Concomitant medications included Amlodipine (Amlodipine), Aspirin (Acetylsalicylic Acid), Atenolol (Atenolol), Atorvastatin (Atorvastatin), Isosorbide Mononitrate (Isosorbide Mononitrate), Metformin (Metformin), Nicorandil (Nicorandil), Gtn (Glyceryl Trinitrate), Novomix (Insulin Aspart, Insulin Aspart Protamine (Crystalline)), Omeprazole (Omeprazole), Quinine Sulphate (Quinine Sulfate), Ramipril (Ramipril), Trazodone (Trazodone), and Naproxen (Naproxen).

The subject received the first dose of blinded investigational study drug on an unknown date. The subject received the last dose of blinded investigational study drug on an unknown date. On PPD, the subject attended end of study (EOS) visit. PPD

The investigator reported that the event Chest pain was not related to blinded investigational drug, to the device or to the study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD. The subject received first dose of blinded investigational study drug on PPD. On PPD echocardiogram showed normal results. On PPD, chest X-ray showed no abnormality. The subject received last dose of blinded investigational study drug on PPD PPD

ADDITIONAL INFORMATION RECEIVED ON PPD: Event term was updated from chest pain to small non-ST elevation MI. Additional medical history included diffuse distal vessel coronary disease. The etiology of the event was cardiac-chest pain. PPD

The investigator reported that the event small non-ST elevation MI was not related to blinded investigational drug, to the device or to the study conduct.

Study Drug :

Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Intramuscular	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Death	Death (Death)	PPD (107 days)

Case Narrative : Information received on PPD this P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and died.

The subject's historical medical condition included PPD PPD . The subject's current medical condition included dyslipidemia, hypertension, generalized anxiety depression, sleep apnoea, obesity, paroxysmal atrial fibrillation, gastritis, duodenitis, Asperger's syndrome, right big toe fungal infection and right knee pain. The subject had no known drug allergy. The subject's concomitant medications included Atorvastatin (atorvastatin), Warfarin (warfarin), Omeprazole (omeprazole), Propranolol (propranolol), Amlodipine (amlodipine), Co-Dydramol (dihydrocodeine bitartrate, paracetamol), Sertraline (sertraline), Clopidogrel (clopidogrel), Terbinafine (terbinafine), and "Bendrphyle". No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . The subject received last dose of blinded investigational drug on PPD End of study visit was performed on PPD PPD

The investigator reported that the event death was not related to blinded investigational study drug, to the device, or to the statin therapy.

ADDITIONAL INFORMATION RECEIVED ON PPD : On PPD the subject had recent general practitioner (GP) visit, "had come out of warfarin". The subject's international normalized ratio (INR) was 1.6 (sub therapeutic). On PPD the subject was treated with clarithromycin for chest infection. The subject had sleep apnoea, hence received continuous positive airway pressure (CPAP) mask and death was not expected. On an unknown date, unspecified examination showed no significant changes. PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Death (unknown cause)	Death (Unknown cause of death)	PPD (734 days)

Case Narrative : Initial Receipt Date = PPD

This P years old male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and died.

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug prior to the event was on PPD . The subject completed the end of study on PPD .PPD .

The investigator reported that the event Death was not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The investigator reported that information regarding primary cause of death was not available at the time of this report.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Subcutaneous	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
acute on chronic heart failure	Cardiac failure acute (Acute on chronic heart failure)	PPD ---

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD female subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and died due to heart failure.

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The subject's medical history included PPD
PPD Previous treatment for the condition under study was not provided. Concomitant medications included clopidogrel, furosemide, gliclazide, and losartan.

The subject received the first dose of blinded investigational study drug on PPD . The subject received the last dose of blinded investigational study drug prior to the event on PPD The subject completed study on PPD The subject did not pass urine since PPD The subject visited general practitioner (GP) who increased dose of furosemide (dose unknown). The subject had heart failure. The subject was unwell since PPD On PPD the subject was hospitalized. On same day, the subject had cardiac arrest and resuscitation was performed for few times. Few hours later, the subject died due to heart failure.

The investigator reported that there was not a reasonable possibility that the fatal event of heart failure was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD Previously reported event term heart failure was updated to acute on chronic heart failure [PT: Cardiac failure acute]. The information regarding relevant diagnostics performed for the event was not available.

The investigator reported that the fatal event Cardiac failure acute was not related to blinded investigational drug or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Decompensated heart failure	Cardiac failure (Decompensated heart failure)	PPD (32 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Shortness of breath [PT: Dyspnoea].

No historical medical condition was reported. The subject's current medical condition included dyslipidaemia, chronic kidney disease, congestive cardiac failure. No relevant concomitant medications were provided.

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The subject received the first dose of blinded investigational study drug on an unknown date. The subject had completed the end of the study visit on an unknown date. PPD

The investigator reported that the event Dyspnoea was not related to blinded investigational drug or device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject received the first dose of blinded investigational study drug on PPD . The subject was treated with intravenous unspecified diuretics and bisoprolol. The subject's last dose of blinded investigational drug was on PPD . The subject completed the study on PPD .

ADDITIONAL INFORMATION RECEIVED ON PPD : Previously reported event term shortness of breath was updated to decompensated heart failure. The investigator confirmed that the subject received blinded investigation drug through subcutaneous route.

The investigator reported that the event decompensated heart failure was not related to blinded investigational drug or device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
chest pain	Chest pain (Chest pain)	PPD (25 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and experienced chest pain [PT: Chest pain].

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The subject's historical medical condition included PPD. The subject's current medical condition included dyslipidaemia, hypercholesterolemia, hypertension, and Type 2 diabetes. Concomitant medications included Atorvastatin (Atorvastatin), Bisoprolol (Bisoprolol), GTN (Glyceryl Trinitrate), Ramipril (Ramipril), Aspirin (Acetylsalicylic Acid), and Lansoprazole (Lansoprazole).

The subject received the first dose of blinded investigational study drug on PPD. The subject's last dose of blinded investigational study drug was on PPD. End of study visit was completed on PPD. PPD

The investigator reported that the event Chest pain was not related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
FEBRILE ILLNESS	Pyrexia (Acute febrile illness)	PPD (402 days)
Neutropenic sepsis	Neutropenic sepsis (Neutropenic sepsis)	PPD (399 days)

Case Narrative : Initial Receipt Date = PPD.

This P year old PPD male subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A

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Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Neutropenic sepsis [PT: Neutropenic sepsis] and FEBRILE ILLNESS [PT: Pyrexia].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. Concomitant medications included Salbutamol (Salbutamol), Aspirin (Acetylsalicylic Acid), Lansoprazole (Lansoprazole), Fluoxetine (Fluoxetine), Beclometasone (Beclometasone), Dexamethasone (Dexamethasone), Sodium Chloride (Sodium Chloride), Movicol (Macrogol 3350, Potassium Chloride, Sodium Bicarbonate, Sodium Chloride), and Carboplatin W/Etoposide (Carboplatin, Etoposide).

The subject received the first dose of blinded investigational study drug on PPD The subject was recent diagnosed with locally advanced small cell lung cancer, large right hilar mass with extensive mediastinal lymph nodes and superior vena cava obstruction (reported separately). The subject was started on chemotherapy with Carboplatin and Etoposide . On PPD the subject completed the study. PPD PPD PPD The subject's last dose of blinded investigational drug prior to the event was on PPD PPD

The investigator reported that the event Pyrexia and Neutropenic sepsis was not related to blinded investigational drug or device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Unknown	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Cardiac arrest	Cardiac arrest (Cardiac arrest)	PPD (74 days)
Sepsis intra abdominal	Abdominal sepsis (Abdominal sepsis)	PPD (33 days)
Small bowel obstruction	Small intestinal obstruction (Small bowel obstruction)	PPD (28 days)

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Case Narrative : Initial Receipt Date = PPD .

This P year old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had fatal event Cardiac arrest [PT: Cardiac arrest], and the events Small bowel obstruction [PT: Small intestinal obstruction], and Sepsis intra abdominal [PT: Abdominal sepsis].

The subject's historical medical condition included PPD (MI) With Stent. The subject's current medical condition included Dyslipidemia. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug was on PPD The end of study was completed on PPD . PPD

The investigator reported that the fatal event Cardiac arrest, and the events small intestinal obstruction, and abdominal sepsis were not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : Additional medical history and predisposing factors for the events included PPD PPD
There was no identified predisposing factors to sepsis. The subject had no history of diabetes, thyroid disease, alcohol intake or recovering alcohol, and drug abuse. The subject's body mass index (BMI) was 24. On unknown date, computerized tomogram (CT) revealed small bowel obstruction likely due to adhesions.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Myocardial infarction	Myocardial infarction (Myocardial infarction)	PPD (42 days)

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Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Myocardial infarction [PT: Myocardial infarction].

The subject's historical medical condition included PPD PPD . The subject's current medical condition included Dyslipidemia, Type 2 Diabetes Mellitus, Peripheral Neuropathy, Retinopathy, Osteoarthritis Knees And Hands, Menopause, Gastro-Oesophageal Reflux, Depression Hypertension, Ex-Smoker. Historical procedures included coronary anigography which revealed Severe stenosis right coronary artery (RCA), Mild/ moderate stenosis left anterior descending (LAD), moderate stenosis left circumflex artery (LCX) and Percutaneous coronary intervention which revealed rotablation and stent to RCA. Concomitant medications included Atorvastatin (Atorvastatin), Asprin (Acetylsalicylic Acid), Bisoprolol (Bisoprolol), Omacor (Omega-3-Acid Ethyl Ester), Losartan (Losartan), GTN (Glyceryl Trinitrate), Metformin (Metformin), Novomix (Insulin Aspart, Insulin Aspart Protamine (Crystalline)), Sertraline (Sertraline), Quinine Sulphate (Quinine Sulfate), Pregabalin (Pregabalin), Esomeprazole (Esomeprazole), Calcichew D3 Forte (Calcium Carbonate, Colecalciferol), Alendronic Acid (Alendronic Acid), Prednisolone (Prednisolone), Azathioprine (Azathioprine), Oxygen (Oxygen), Co-Codamol (Codeine Phosphate, Paracetamol).

The subject received the first dose of blinded investigational study drug on PPD In PPD the subject had fatty liver and multiple gallstones. Also in PPD the subject had echocardiogram which showed normal Left ventricular systolic function. On PPD the subject completed the end of study. PPD

PPD . The subject's last dose of blinded investigational drug prior to the event was on PPD . The outcome of the event Myocardial infarction was reported as Not Recovered/Not Resolved.

The investigator reported that the event Myocardial infarction was not related to blinded investigational drug and study device.

ADDITIONAL INFORMATION RECEIVED ON PPD Additional medical history included PPD The subject had no known allergies. Additional concomitant medications included clopidogrel, heparin sodium, omeprazole, rifampicin, teicoplanin, lansoprazole, and paracetamol. PPD
PPD

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PPD

Study Drug :

Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
ACUTE KIDNEY INJURY	Acute kidney injury (Acute kidney injury)	PPD (15 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed ACUTE KIDNEY INJURY [PT: Acute kidney injury].

The subject's historical medical condition included PPD The subject's current medical condition included Dyslipidemia and Hypertension. The subject's surgical procedure included Percutaneous coronary intervention (PCI), Stent Placement, and Sub-total thyroidectomy. Concomitant medications included Atorvastatin (Atorvastatin), Aspirin (Acetylsalicylic Acid), Bisoprolol (Bisoprolol), and Ramipril (Ramipril).

The subject received the first dose of blinded investigational study drug on PPD On PPD the subject underwent left ureteric stone removal and laser lithotripsy. On PPD the subject's right ureteric stone was removed and temporary ureteric stent placement was performed. The subject's last dose of blinded investigational drug prior to the event was on PPD. On PPD the subject completed the study. P P D

The investigator reported that the event Acute kidney injury was not related to blinded investigational drug and device.

ADDITIONAL INFORMATION RECEIVED ON PPD : Previously reported medical history hypothyroidism was updated to current condition. There

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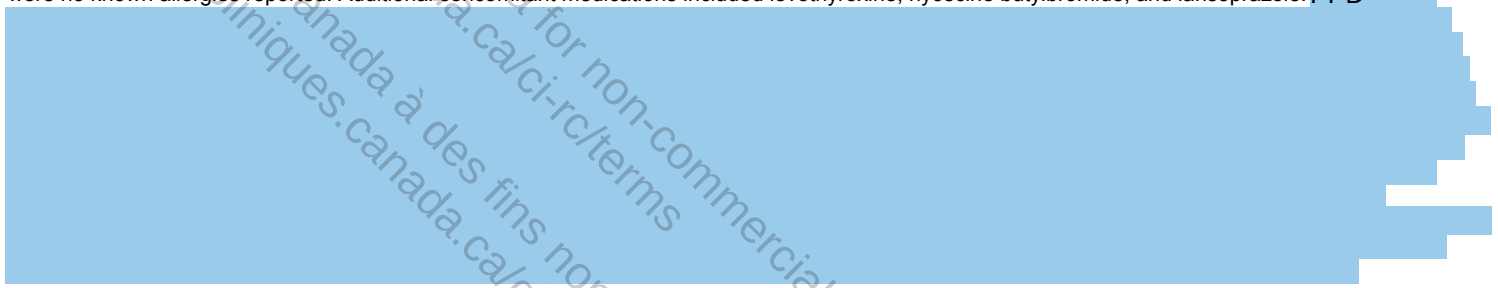
were no known allergies reported. Additional concomitant medications included levothyroxine, hyoscine butylbromide, and lansoprazole. PPD



Study Drug : placebo

Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

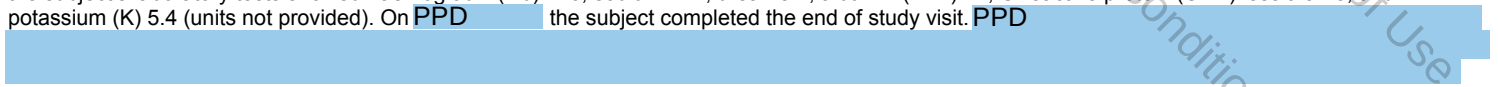
SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
gastroesophageal reflux disease	Gastrooesophageal reflux disease (Gastroesophageal reflux disease)	PPD (33 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD female subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed vomiting and abdominal pain.

The subject's medical history included PPD . Previous treatment for the condition under study was not provided. No relevant concomitant medications were reported.

The subject received the first dose of blinded investigational study drug on PPD . Approximately one year and seven months later on PPD the subject's laboratory tests showed haemoglobin (Hb) 116, sodium 141, urea 18.2, albumin (ALB) 41, C-reactive protein (CRP) less than 5, and potassium (K) 5.4 (units not provided). On PPD the subject completed the end of study visit. PPD



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PPD
PPD The subject received the last dose of blinded investigational study drug prior to the event on PPD .

The causal relationship between the events vomiting and abdominal pain and blinded investigational study drug was not provided by the investigator. However, there was not a reasonable possibility that the events vomiting and abdominal pain was related to study device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The investigator reported that there was not a reasonable possibility that the events vomiting and abdominal pain were related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD 6: Additional medical history included PPD
PPD
PPD The subject did not have any history of allergy. Additinal concomitant medication included insulin. PPD
PPD

PPD

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PPD

ADDITIONAL INFORMATION RECEIVED ON PPD : Previously reported events vomiting and abdominal pain were deleted and updated to final diagnosis of gastroesophageal reflux disease. The subject had acute kidney injury due to unspecified nephrotoxic drug. Additionally, there was a fluid loss due to vomiting. As per the investigator, the events acute kidney injury and urinary tract infection did not meet the criteria for reporting as separate serious adverse events (SAEs) as per the ICH guidelines. PPD The outcome of the event gastroesophageal reflux disease was reported as resolved on PPD.

The investigator reported that there was not a reasonable possibility that the event gastroesophageal reflux disease was related to blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The outcome of the event gastrooesophageal reflux disease was reported as resolved on PPD (previously reported as PPD).

Version created in error on PPD.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Intramuscular	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Stroke	Cerebrovascular accident (Stroke)	PPD (18 days)

Case Narrative : Initial Receipt Date = PPD.

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and had stroke.

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The subject's medical history included PPD. Previous treatment for the condition under study was not reported. Concomitant medications included amlodipine, Aspirin (acetylsalicylic acid), atenolol, lisinopril and linagliptin.

The subject received the first dose of blinded investigational study drug on PPD. On unknown date in PPD the subject had stroke. The subject's last dose of blinded investigational study drug was on PPD. The end of study visit was performed on PPD PPD

The investigator reported that there was not a reasonable possibility that the event stroke was related to blinded investigational study drug or to the device or to study conduct.

ADDITIONAL INFORMATION RECEIVED ON PPD

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Intramuscular	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Gastroenteritis	Gastroenteritis (Gastroenteritis)	PPD (18 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD female subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing

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the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed gastroenteritis.

The subject's medical history included PPD .
Previous treatment for the condition under study was not provided. Concomitant medications included atorvastatin, clopidogrel, and levetiracetam.

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject completed the study. P PPD PPD . The subject's last dose of blinded investigational study drug was on PPD .

The investigator reported that there was not a reasonable possibility that the event gastroenteritis was related to the blinded investigational study drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The investigator reported that the subject's risk factors were not identified.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
congestive heart failure exacerbation/worsening systolic and diastolic congestive heart failure	Cardiac failure congestive (Congestive heart failure)	PPD (146 days)
pneumonia	Pneumonia (Pneumonia)	PPD (18 days)

Case Narrative : Initial Receipt Date = PPD .

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This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed congestive heart failure exacerbation and pneumonia.

The subject's medical history included PPD
PPD
PPD . Previous treatment for the condition under study was not reported. Concomitant medications included metolazone and Lasix (furosemide).

The subject received the first dose of blinded investigational study drug on PPD . The subject received the last dose of blinded investigational study drug prior to event on PPD . The subject completed the study on PPD . PPD

PPD

The investigator reported that there was not a reasonable possibility that the events congestive heart failure exacerbation and pneumonia were related to blinded investigational study drug and to the device.

PPD

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PPD

The investigator reported that there was not a reasonable possibility that the fatal event of worsening systolic and diastolic congestive heart failure was related to blinded investigational study drug or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Atypical chest pain	Chest pain (Chest pain)	PPD ---

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and had Atypical chest pain [PT: Chest pain].

The subject's historical medical condition included PPD PPD The subject's current medical condition included Dyslipidemia, coronary artery disease (CAD), Atypical Chest Pain, hypertension (HTN), Hyperlipidemia, and Chronic Back Pain. The subject's surgical history included PPD PPD . The subject did not have history of any known drug allergy and alcohol use. The subject's family history included PPD PPD . Concomitant

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medications included Atorvastatin (Atorvastatin), Aspirin (Acetylsalicylic Acid), Ranexa (Ranolazine), Nitroglycerin (Glyceryl Trinitrate), Plavix (Clopidogrel Bisulfate), Coreg (Carvedilol), Losartan (Losartan), Protonix (Omeprazole), Tizanidine (Tizanidine), Hydrocortisone (Hydrocortisone), "opioid therapy", Florinef (Fludrocortisone Acetate), Oxycodone (Oxycodone), Acetaminophen (Paracetamol), Isosorbide Mononitrate (Isosorbide Mononitrate), Gabapentin (Gabapentin), Zyrtec (Cetirizine Hydrochloride), Pantoprazole (Pantoprazole), Biotin (Biotin), Norco (Hydrocodone Bitartrate, Paracetamol), and Ranolazine (Ranolazine).

The subject received the first dose of blinded investigational study drug on an unknown date. The subject's received last dose of blinded investigational drug on an unknown date. On an unknown date, the subject completed the study and rolled over to open label phase of study and received first dose of investigational study drug PPD PPD

The investigator reported that the event Chest pain was not related to blinded investigational study drug and to the device.

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ADDITIONAL INFORMATION RECEIVED ON PPD : The investigator reported that chest pain was "peosoticy pop" costochondritis.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
ELEVATED ALT	Alanine aminotransferase increased (ALT increased)	PPD (20 days)
ELEVATED AST	Aspartate aminotransferase increased (AST increased)	PPD (20 days)

Case Narrative : Initial Receipt Date = PPD

This P years, old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed ELEVATED AST [PT: Aspartate aminotransferase increased] and ELEVATED ALT [PT: Alanine aminotransferase increased].

The subject's historical medical conditions included PPD . The subject's current medical conditions included Dyslipidaemia, gastroesophageal reflux disease (GERD), Tobacco use, and alcohol (ETOH) use. The subject's historical procedures included PPD PPD . Concomitant medications included Atorvastatin (Atorvastatin) (advised to stop), Atenolol (Atenolol) and Hydrochlorothiazide (Hydrochlorothiazide).

The subject received the first dose of blinded investigational study drug on PPD On PPD the subject's laboratory tests showed alanine aminotransferase (ALT) 34 U/L and aspartate aminotransferase (AST) 22 U/L. On PPD laboratory tests showed ALT 36 U/L and AST 30 U/L. On PPD laboratory tests showed ALT 91 U/L and AST 48 U/L. The subject received the last dose of blinded investigational study drug on PPD and on PPD the subject completed end of study (EOS). PPD

The investigator reported that the events Alanine aminotransferase increased and Aspartate aminotransferase increased were not related to blinded investigational drug or to the device.

Study Drug : Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	66186	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Acute coronary syndrome	Acute coronary syndrome (Acute coronary syndrome)	PPD (17 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Acute coronary syndrome [PT: Acute coronary syndrome].

The subject's historical medical condition included PPD . The subject's current medical condition included Dyslipidaemia and Hyperlipidaemia. Surgical history included PPD Concomitant medications included Plavix (Clopidogrel Bisulfate), Imdur (Isosorbide Mononitrate), Altace (Ramipril), and Ranexa (Ranolazine).

The subject received the first dose of blinded investigational study drug on PPD . On an unknown date in PP , the subject underwent stent placement. On PPD , the subject completed end of study visit. PPD

The investigator reported that the event Acute coronary syndrome was not related to blinded investigational drug and to conduct of study.

ADDITIONAL INFORMATION RECEIVED ON PPD Additional medical history included allergy to PPD PPD

PPD The subject did not have history of alcohol use, substance abuse, tobacco use,

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PPD

Additional concomitant medications included naproxen, ramipril, metoprolol succinate, Crestor (rosuvastatin calcium), isosorbide, clopidogrel, ezetimibe, and Tylenol with codeine (codeine phosphate, paracetamol).

In PPD, the subject underwent catheterization. At that time, the subject had placement of drug-eluting stents to the distal left anterior descending artery, patent LIMA to the left anterior descending artery, occluded vein grafts and patent stents to the right coronary artery and obtuse marginal. P

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PPD

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PPD

The investigator reported that the event Acute coronary syndrome was not related to device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Unknown	---	---

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
death	Death (Death)	PPD ---

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Case Narrative : Information received on PPD this P years old, PPD male subject (number: 11866257008) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and died.

The subject's historical medical condition included PPD The subject's surgical history included PPD The subject's current medical condition included dyslipidemia, coronary artery disease, hyperlipidemia, alcohol abuse, hypertension, chronic low back pain, chronic obstructive pulmonary disease (COPD), alcohol use, smoker, alcoholic hepatitis, tobacco use. The subject had drug allergy of lisinopril. The subject's concomitant medications included Atorvastatin (atorvastatin), Albuterol (salbutamol), Aspirin (acetylsalicylic acid), Hydralazine (hydralazine), Metoprolol (metoprolol), Lorazepam (lorazepam), Losartan (losartan), Lopressor (metoprolol tartrate), Dulera (formoterol fumarate, mometasone furoate), Nitroglycerine (glyceryl trinitrate), Spiriva (tiotropium bromide), Dyazide (hydrochlorothiazide, triamterene), Folic Acid (folic acid), Nicoderm (nicotine), Pantoprazole (pantoprazole), Thiamine (thiamine), Vitamin B (vitamin B complex), Ventolin Hfa (salbutamol sulfate). No co-suspect medications were reported.

The subject received the first dose of blinded investigational study drug on unknown date. After unspecified time frame on PPD , subject completed end of study visit. PPD

PPD

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PPD

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PPD

The investigator reported that the event Death was not related to blinded investigational drug and to the device.

Study Drug :

Study Drug Administered : Yes

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Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Non ST elevation myocardial infarction	Acute myocardial infarction (Non ST segment elevation myocardial infarction)	PPD (12 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD female subject (number: PPD was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed Non ST elevation myocardial infarction [PT: Acute myocardial infarction]

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia, and Coronary Artery Disease. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . The subject's end of study was reported on PPD . PPD

The investigator reported that the event Acute myocardial infarction was not related to blinded investigational drug, or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Non st segment elevation MI	Acute myocardial infarction (Non ST segment elevation myocardial infarction)	PPD (28 days)

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Case Narrative : Initial Receipt Date = PPD .

This P years old male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed Non ST segment elevation MI [PT: Acute myocardial infarction].

The subject's historical medical condition included PPD . The subject's current medical condition included Dyslipidaemia, coronary artery disease (CAD), and Hypertension. The subject had allergy of sulfa drug and tetanus. The subject's surgical history included PPD PPD Concomitant medications included Simvastatin (Simvastatin), Aspirin (Acetylsalicylic Acid), and Carvedilol (Carvedilol).

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational drug on PPD On the same day, the subject completed end of study visit. PPD PPD

The investigator reported that the event Acute myocardial infarction was not related to blinded investigational drug and device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
coronary artery disease	Coronary artery disease (Coronary artery disease)	PPD (48 days)

Case Narrative : Initial Receipt Date = PPD

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed chest pain.

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The subject's medical history included PPD

PPD

PPD

The subject's family history included PPD Previous treatment for the condition under study was not reported. Concomitant medications included Nitroglycerin (glyceryl trinitrate), Aspirin (acetylsalicylic acid), lisinopril, Acetaminophen w/caffeine (caffeine, paracetamol), metoprolol succinate, Norco (hydrocodone bitartrate, paracetamol), Procardia (nifedipine), simvastatin, Imdur (isosorbide mononitrate), Ranexa (ranolazine), isosorbide mononitrate, and Ranitidine HCL (ranitidine hydrochloride).

The subject received the first dose of blinded investigational study drug on PPD Approximately six months later on PPD echocardiogram showed ejection fraction (EF) 50-55%, mild mitral regurgitation (MR), mild aortic regurgitation (AR), and trace tricuspid regurgitation (TR). On PPD catheterization showed in left main 20% stenosis, proximal left anterior descending (LAD) 30% stenosis, mild/distal, and luminal irregularities. First right posterolateral artery had 100 % stenosis. On an unknown date in PPD catheterization showed non obstructive disease in left coronary artery (LCA), patent proximal and mid right coronary artery (RCA) stents and 100 % in-stent posterior left ventricular branch (PLVB) restenosis resulting in coronary total occlusion (CTO). On PPD Holter monitoring showed isolated premature ventricular contractions (PVCs) in bigeminy or trigeminy. On PPD catheterization showed no significant changes. On PPD echocardiogram showed EF 45-50%, mild to moderate left ventricular hypertrophy (LVH), grade 1 DD, trace MR, and trivial pulmonary regurgitation (PR). On PPD chest x-ray showed no acute disease. On PPD echocardiogram showed EF 35-40%, grade1 DD, trace MR, minimal aortic regurgitation (AR), and trace tricuspid regurgitation (TR). On the same day, stress test showed EF 25%. Images demonstrated large sized partially paradoxical reverse distribution perfusion abnormality of severe intensity in the basal inferior, basal inferolateral, mild inferior, mild inferolateral and apical lateral myocardial walls consistent with gastrointestinal (GI) uptake artifact and prior MI.

On PPD the subject's laboratory test noted creatinine 1.99 mg/dl. On an unknown date in PPD catheterization showed 90% in-stent restenotic lesions in distal right coronary artery (RCA) that was treated with drug-eluting stents (DES) with PCI. The posterior left ventricular (PLV) branch had a CTO of multiple previously placed stents and was left alone for medical management. On PPD catheterization showed PCI with drug-eluting stent placement to the distal right coronary artery.

The subject received last dose of blinded investigational study drug on PPD . The subject completed the study on an unknown date. P

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PPD

The investigator reported that there was not a reasonable possibility that the event chest pain was related to blinded investigational study drug or to the device.

DDITIONAL INFORMATION RECEIVED ON PPD : Previously reported event term chest pain was updated to coronary artery disease. Additional medical history included PPD The subject's family history included PPD . The investigator clarified the meaning of previously reported family history PPD . On PPD the study was ended. PPD

The investigator reported that there was not a reasonable possibility that the event coronary artery disease was related to blinded investigational study drug or to the device.

PPD

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PPD

PPD The investigator confirmed that the subject received last dose of investigational study drug prior to the event on PPD .

ADDITIONAL INFORMATION RECEIVED ON PPD

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
cardiac ischemic event stemi	Myocardial ischaemia (Ischemic heart disease)	PPD (25 days)
coronary artery revascularization	Coronary revascularisation (Coronary revascularization)	PPD (25 days)

Case Narrative : Initial Receipt Date = PPD .

This P year old, PPD male subject was participating in a clinical trial, a double-blind, randomized, placebo-controlled, multicenter study assessing the impact of additional LDL-cholesterol reduction on major cardiovascular events when AMG 145 is used in combination with statin therapy in patients with clinically evident cardiovascular disease and developed cardiac ischemic event STEMI and underwent coronary artery revascularization.

The subject's medical history included PPD PPD . Previous treatment for the condition under study was not reported. Concomitant medications included atorvastatin and prasugrel.

The subject received the first dose of blinded investigational study drug on PPD The subject received the last dose of blinded investigational study drug prior to the event on PPD . The investigator reported that the study was ended. PPD

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PPD

The investigator reported that there was not a reasonable possibility that the events cardiac ischemic event STEMI and coronary artery revascularization were related to blinded investigational study and study device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	Yes		UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Cardiac ischemic event	Myocardial ischaemia (Cardiac ischemia)	PPD (799 days)
Death	Death (Death)	PPD (799 days)

Case Narrative : Initial Receipt Date = PPD

This P year old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and died due to Cardiac ischemic event [PT: Myocardial ischaemia].

The subject's historical medical condition included PPD . The subject's current medical condition included Dyslipidemia, Coronary Artery Disease (CAD), Cardiomyopathy and Diabetes Mellitus Type 2. The subject's surgical procedures included stent, automatic implantable cardioverter-defibrillator (AICD) implantation and mechanical aortic valve. No relevant concomitant medications were provided.

The subject received the first dose of blinded investigational study drug on PPD . The subject's last dose of blinded investigational study drug was on PPD The subject performed end of study visit on PPD . PPD

The investigator reported that the event death and fatal event of Myocardial ischaemia were not related to blinded investigational study drug or to the

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device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
Bronchitis	Bronchitis (Bronchitis)	PPD (20 days)

Case Narrative : Initial Receipt Date = PPD

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease, developed Bronchitis [PT: Bronchitis].

The subject's historical medical condition included PPD The subject's current medical condition included Dyslipidemia, Chronic Obstructive Pulmonary Disease, and Frequent Bronchitis. Concomitant medications included Atorvastatin (Atorvastatin), Atenolol (Atenolol), Aspirin (Acetylsalicylic Acid), Persantin (Dipyridamole), and Esopram (Escitalopram Oxalate).

The subject received the first dose of blinded investigational study drug on PPD The subject received last dose of blinded investigational study drug on PPD . Two days later onPPD , end of study visit was performed. PPD

The investigator reported that the event Bronchitis was not related to blinded investigational drug, or to the device.

Study Drug : Study Drug Administered : Yes

Case Number	Study ID	Patient ID	Center ID	Related Case	Death Case	Death Date	Dose	Patient Route of Administration	Frequency	Last Dose
PPD	20110118.2	PPD	PP	No	No	---	UNK	Subcutaneous	---	PPD

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SAE Reported Term	SAE Preferred Term (SAE Lower Level Term)	Onset Date (Time to Onset)
TIA	Transient ischaemic attack (TIA)	PPD ---

Case Narrative : Initial Receipt Date = PPD .

This P years old PPD male subject (number: PPD) was participating in an Amgen-sponsored clinical trial, with study number 20110118.2, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy in Patients with Clinically Evident Cardiovascular Disease and developed TIA [PT: Transient ischaemic attack].

No historical medical condition was reported. The subject's current medical condition included Dyslipidemia. Concomitant medications included Aspirin (Acetylsalicylic Acid).

The subject received the first dose of blinded investigational study drug on PPD . On PPD , the subject completed the end of study visit. P P D

The investigator reported that the event Transient ischaemic attack was not related to blinded investigational drug or to the device.

ADDITIONAL INFORMATION RECEIVED ON PPD : The subject had medical history of PPD The subject did not have history of diabetes, smoking, hypertension and stroke. PPD PPD PPD

Study Drug : AMG 145

Study Drug Administered : Yes

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PPD

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