SUPPLEMENTAL MATERIAL

Supplemental Methods. Inclusion and exclusion criteria

Inclusion criteria

1. Male or female aged 18 years to 80 years at the time of providing informed consent.
2. Subjects must have documented evidence of a history of atherosclerotic coronary artery disease/surgical revascularization (defined as either a prior myocardial infarction, percutaneous coronary intervention or coronary artery bypass graft surgery) or peripheral vascular disease (defined by prior percutaneous or surgical peripheral revascularization procedure). Documentation of atherosclerotic disease must be provided. A minimum of 1 month must have elapsed between a subject's randomization and any acute event, revascularization procedure, or hospitalization for chest pain for that subject.
3. Subjects must be taking 2 antiplatelet medications (with appropriate medical indication) with a stable dose for a minimum of 1 month before randomization. These antiplatelet medications must comprise:
    - Aspirin (75 to 325 mg per day).
    - A P2Y12 receptor antagonist, either clopidogrel (75 mg per day) or prasugrel (10 mg per day).
4. Subjects must be on a stable medication regimen for chronically administered therapy for a minimum of 2 weeks or 5 half-lives (whichever is longer) before randomization and must remain on this stable medication regimen throughout the active study period.
5. Body weight 50 kg or greater at screening.

6. Capable of understanding the purposes and risks of the study and able to provide written informed consent before any study-specific screening procedures are performed.
7. Willing and able to adhere to all protocol requirements.
8. Female subjects with a negative urine or serum pregnancy test or who are post-menopausal (menopause is defined as over the age of 60 years, or women between the ages 45 and 60 years who are amenorrheic for at least 1 year and have a follicle-stimulating hormone level >30 IU/L). Females of childbearing potential must be practicing adequate birth control during the study and for 3 months after receipt of the study product to be eligible. Acceptable methods of birth control are oral contraceptives, intrauterine device, female and male condoms with foam or spermicidal jelly, diaphragm, contraceptive medication patch, contraceptive medication implant, contraceptive medication injection, abstinence, or surgical sterilization more than 3 months prior to randomization.
9. Male subjects must agree to use effective contraception (i.e., condom with foam or spermicidal jelly, vasectomy, or abstinence) during the study and for 3 months after the receipt of study product.
10. Willing not to participate in another interventional clinical study until completion of the follow-up study period final (Day 90) visit.

Exclusion criteria

1. A history of unexplained syncope, known Long QT syndrome, or Brugada syndrome. Subjects will also be excluded if there is family history of Long QT syndrome.

2. New York Heart Association class III or IV heart failure or documented cardiac ejection fraction of <35%.
3. Renal function that is moderate or severely impaired (CrCl <60 mL/min) [calculated using the Cockcroft-Gault formula].
4. For subject with diabetes mellitus, recent (within 30 days of admission) unstable glycemic control defined as: >1 hypoglycemic episode, hypoglycemic unawareness, or hyperglycemia requiring hospitalization.
5. Evidence of hepatobiliary disease as indicated by any of the following:
    - Previous medical history of liver disease or chronic hepatic dysfunction, including cirrhosis, hepatitis, or biliary obstruction with hyperbilirubinemia (with the exception of a remote history of hepatitis due to cytomegalovirus, Epstein–Barr virus, or hepatitis A)
    - Elevated ALT, AST, or total bilirubin test results (at or above 1.5x ULN) either at screening and/or at Day -2
    - Evidence of active cholecystitis, gall bladder symptoms, or potential hepatobiliary abnormalities at screening or at Day -2
6. Subjects who have been a recipient of an organ transplant or are currently taking immunosuppressant drugs.
7. History of malignancy within the 5 years before the receipt of study product with the exception of the following, which have been treated without recurrence: stage 1 carcinoma of the cervix; stage 1 carcinoma of the prostate; basal cell carcinoma (within 2 years of receipt of study product).

8. Evidence of a medically unstable condition, disorder, or disease within 30 days of randomization, including any of the following:
    - Acute coronary syndrome, transient ischemic attack, stroke, or peripheral vascular disease; clinically significant active bleeding (with the exception of menstruating women); acute or chronic hepatic (hepatitis, cirrhosis); biliary; renal (other than diabetic nephropathy in subjects with diabetes); bronchopulmonary; hematologic; gastrointestinal (other than gastroesophageal reflux disease); allergy; endocrine/metabolic (untreated thyroid disorders, adrenal disease); psychiatric; immunodeficiency
    - A sustained supine systolic blood pressure >160 mmHg or <90 mmHg; or a diastolic blood pressure >90 mmHg or <50 mmHg, at screening or Day -2. Blood pressure may be retested twice after initial assessment in the supine position at 5-minute intervals (for a total of three blood pressure assessments). The pressure elevation is considered sustained if either the systolic or the diastolic pressure values are outside the stated limits for all three assessments
9. A pulse rate at rest of <45 bpm or >100 bpm.
10. Any clinically relevant abnormal laboratory test results at screening, which are indicative of an active or uncontrolled medical illness with the exception of total cholesterol, HDL-C, and LDL-C, or triglycerides.
11. Thrombocytopenia defined as a platelet count of <150,000 per μL at screening.
12. Evidence of a coagulopathy as indicated by:
    - Previous medical history of a bleeding disorder or coagulopathy
    - Treatment with warfarin or dabigatran (within three months of randomization)

- Treatment with glycoprotein IIb/IIIa inhibitor (within one month of randomization)
- Abnormal coagulation test results (at screening and/or at Day -2)

13. Subjects taking clopidogrel who show evidence of poor clopidogrel metabolism as indicated by rapid genotype testing performed at the screening visit. Subjects taking prasugrel will not undergo genetic testing for clopidogrel metabolism.
14. Receipt of sustained treatment with a combination of omeprazole and clopidogrel within one month prior to randomization.
15. Subjects with an inability to interrupt any prescription or non-prescription medications that inhibit platelet function or inhibit coagulation. However, aspirin and clopidogrel or prasugrel are permitted medications. Non-steroidal anti-inflammatory drugs (including but not limited to ibuprofen, naproxen, salsalate, indomethacin, ketorolac, diclofenac, and celecoxib) are prohibited preceding randomization for the following durations, whichever is longer:
    - For the seven days preceding randomization
    - For the length of time equivalent to five times the elimination half-life
16. Uncontrolled and clinically significantly altered ECG rhythm or morphology within 2 months of randomization.
17. Subjects who have an abnormal screening electrocardiogram indicating a second- or third-degree atrioventricular block, or one or more of the following:
    - Left branch bundle block
    - Corrected QT interval >480 ms
    - PR interval >260 ms

- Any rhythm other than sinus rhythm or stable rate-controlled atrial fibrillation, which is interpreted by the investigator to be clinically significant

18. A positive hepatitis B, hepatitis C, or HIV test result at screening. If a positive hepatitis B or C serology is seen and the investigator determines that the subject has evidence of previous vaccination with respective positive serology, the investigator must contact the medical monitor to assess possible study entry.
19. A positive history of immunoglobulin deficiency or antibodies to immunoglobulin.
20. Known hypersensitivity to soy bean or peanuts.
21. Evidence or history of substance or alcohol abuse at screening, including positive urine test results for drugs of abuse or positive breath test for alcohol.
22. The consumption of alcohol within 48 hours of randomization.
23. Donation or loss of >500 mL of blood within the three months preceding randomization.
24. Participating in another clinical study involving another investigational product or extensive blood sampling within three months of randomization.
25. Subject is pregnant or lactating, or planning to become pregnant during the study period.
26. Any issues that, in the opinion of the investigator, would render the subject unsuitable for study participation.