SUPPLEMENTAL MATERIAL

Bempedoic acid in patients with type 2 diabetes mellitus, prediabetes, and normoglycaemia: a post hoc analysis of efficacy and glycaemic control using pooled data from phase 3 clinical trials.

TABLE S1. Shift Table for Glycaemic Control by Baseline Category (Crude Incidence)

	Post-Baseline Glycaemic Control Status, % (n)			
Baseline Glycaemic Control Status	**Normoglycaemia[d]**	**Prediabetes[e]**	**New Onset Diabetes[f]**	**Undetermined[g]**
Normoglycaemia[a]				
Bempedoic acid (n = 410)	67.8 (278)	22.9 (94)	0.5 (2)	8.8 (36)
Placebo (n = 208)	70.7 (147)	21.6 (45)	0.5 (1)	7.2 (15)
Prediabetes[b]				
Bempedoic acid (n = 1259)	23.4 (295)	64.0 (806)	4.5 (57)	8.0 (101)
Placebo (n = 609)	25.8 (157)	63.5 (387)	5.9 (36)	4.8 (29)
	Last HbA1c Level, % (n)			
	≤ 5.6%	**5.7 – 6.4%**	**≥ 6.5%**	**Undetermined**
Diabetes with HbA1c ≥ 6.5% at baseline[c]				
Bempedoic acid (n = 455)	1.1 (5)	15.2 (69)	74.5 (339)	9.2 (42)
Placebo (n = 232)	0	14.2 (33)	80.6 (187)	5.2 (12)

[a]Patients not fulfilling the criteria for diabetes or prediabetes.
[b]Patients with all the following: no medical history of diabetes; not receiving diabetes medication prior to baseline; and HbA1c of 5.7% to 6.4% (inclusive) at baseline, or ≥1 fasting glucose value of ≥100 mg/dL, but not more than 1 value ≥126 mg/dL between screening and randomization.
[c]Patients with 1 or more of the following: history of type 1 or type 2 diabetes; receiving diabetes medication prior to baseline; and/or HbA1c ≥6.5% at baseline, or ≥1 fasting plasma glucose value ≥100 mg/dL, but not more than 1 value ≥126 mg/dL between screening and randomization. All patients with diabetes in this analysis had HbA1c ≥6.5^ at baseline.
[d]Post-baseline criteria for normoglycemic included HbA1c ≤5.6% and no diabetes medication added.
[e]Post-baseline criteria for prediabetes included HbA1c 5.7 – 6.4% and no diabetes medication added.
[f]Patients with 1 or more of the following: ≥1 HbA1c value ≥6.5%; ≥2 fasting serum glucose values ≥126 mg/dL; an investigator-reported diabetes-related adverse event; and/or initiation of diabetes medication at any point after baseline.
[g]Undetermined due to absence of post-baseline HbA1c levels.
Abbreviations: HbA1c, glycated haemoglobin.

TABLE S2 Safety overview

Parameter	Exposure-Adjusted Incidence, per 100 Person-Years (*n*)					
	Diabetes[a]		Prediabetes[b]		Normoglycaemia[c]	
	BA (*n* = 755)	Placebo (*n* = 380)	BA (*n* = 1259)	Placebo (*n* = 609)	BA (*n* = 410)	Placebo (*n* = 208)
Any TEAE	86.5 (552)	86.3 (290)	86.7 (917)	79.0 (427)	89.6 (302)	88.6 (151)
TEAE leading to IMP discontinuation	12.4 (79)	10.4 (35)	14.4 (152)	6.8 (37)	12.5 (42)	12.3 (21)
Most common TEAEs ≥5 per 100 PY (*n*) in any group						
Nasopharyngitis	8.0 (51)	6.8 (23)	8.4 (89)	13.0 (70)	11.9 (40)	7.6 (13)
Urinary tract infection	6.7 (43)	7.4 (25)	4.4 (47)	5.2 (28)	5.9 (20)	7.6 (13)
Myalgia	4.9 (31)	6.3 (21)	6.5 (69)	5.7 (31)	5.3 (18)	6.5 (11)
Upper respiratory tract infection	4.9 (31)	3.0 (10)	4.5 (48)	5.2 (28)	4.5 (15)	3.5 (6)
Hypoglycaemia	4.5 (29)	5.7 (19)	0.6 (6)	0.7 (4)	1.5 (5)	0.6 (1)
Arthralgia	4.4 (28)	5.4 (18)	5.2 (55)	4.8 (26)	5.0 (17)	7.6 (13)
Dizziness	4.4 (28)	5.4 (18)	3.5 (37)	3.3 (18)	5.3 (18)	2.9 (5)
Diarrhoea	4.1 (26)	6.0 (20)	4.1 (43)	3.0 (16)	3.9 (13)	1.8 (3)
Muscle spasm	3.4 (22)	3.3 (11)	4.5 (48)	3.1 (17)	5.6 (19)	1.8 (3)
Osteoarthritis	3.0 (19)	3.3 (11)	1.9 (20)	2.8 (15)	2.7 (9)	5.3 (9)
Angina pectoris	2.4 (15)	3.0 (10)	2.5 (26)	2.0 (11)	2.4 (8)	5.3 (9)

Note: TEAE incidence is defined as the number of patients having an event started in a certain period divided by the total person-time (in 100 PY) at risk during this period.
[a]Patients with 1 or more of the following: history of type 1 or type 2 diabetes; receiving diabetes medication prior to baseline; and/or HbA1c ≥6.5% (48 mmol/mol) at baseline, or ≥1 fasting plasma glucose value ≥100 mg/dL, but not more than 1 value ≥126 mg/dL between screening and randomization.
[b]Patients with all the following: no medical history of diabetes; not receiving diabetes medication prior to baseline; and HbA1c of 5.7% (39 mmol/mol) to 6.4% (46 mmol/mol) (inclusive) at baseline, or ≥1 fasting glucose value of ≥100 mg/dL, but not more than 1 value ≥126 mg/dL between screening and randomization.
[c]Patients not fulfilling the criteria for diabetes or prediabetes.
Abbreviations: BA, bempedoic acid; HbA1c, glycated haemoglobin; IMP, investigational medicinal product; PY, person-years; TEAE, treatment-emergent adverse event.