Clinical trial results:
A Multi-Center, Open Label, Extension Study Evaluating the Safety and Efficacy of Bomedemstat for the Treatment of Patients with Myeloproliferative Neoplasms (MPNs) Enrolled in a Prior Bomedemstat Clinical Study

Summary

EudraCT number	2021-002452-37
Trial protocol	DE IT
Global end of trial date	22 August 2024

Results information

Result version number	v1
This version publication date	03 September 2025
First version publication date	03 September 2025

Trial information

Trial identification

Sponsor protocol code	IMG-7289-CTP-202

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05223920
WHO universal trial number (UTN)	-
Other trial identifiers	IMG-7289-CTP-202: Imago Bio, 3543-005: MSD

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@msd.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 August 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 August 2024
Global end of trial reached?	Yes
Global end of trial date	22 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a multi-center, open-label extension study to assess the long-term safety and efficacy of bomedemstat administered orally once daily in patients with a Myeloproliferative Neoplasm (MPN) who participated in a prior bomedemstat study such as, but not limited to, IMG-7289-CTP-102/MK-3543-002 (NCT03136185) and IMG-7289-CTP-201/MK-3543-003 (NCT04254978) (referred to hereafter as 'feeder studies').

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 December 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	10 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 15
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Hong Kong: 27
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	New Zealand: 5
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	United States: 9
Worldwide total number of subjects	81
EEA total number of subjects	17

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	37
From 65 to 84 years	42
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Participants with Myeloproliferative Neoplasms (MPNs) who participated in a prior bomedemstat study such as, but not limited to, IMG-7289-CTP-102/MK-3543-002 (NCT03136185) and IMG-7289-CTP-201/MK-3543-003 (NCT04254978) (referred to hereafter as 'feeder studies') were included in the recruitment.

Pre-assignment

Screening details:

Participants were assigned to either the Essential thrombocythemia (ET) arm or Myelofibrosis (MF) arm based on prior diagnosis.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Essential thrombocythemia (ET)

Arm description:

Participants with ET received bomedemstat daily as an oral capsule. The daily dose of bomedemstat was titrated for each participant to a dose that reduced platelets to the target range associated with the participant's underlying MPN.

Arm type	Experimental
Investigational medicinal product name	Bomedemstat
Investigational medicinal product code	
Other name	IMG-7289 MK-3543
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

As titrated per participant

Arm title	Myelofibrosis (MF)

Arm description:

Participants with MF received bomedemstat daily as an oral capsule. The daily dose of bomedemstat was titrated for each participant to a dose that reduced platelets to the target range associated with the participant's underlying MPN.

Arm type	Experimental
Investigational medicinal product name	Bomedemstat
Investigational medicinal product code	
Other name	IMG-7289 MK-3543
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

As titrated per participant

Number of subjects in period 1	Essential thrombocythemia (ET)	Myelofibrosis (MF)
Started	52	29
Completed	0	0
Not completed	52	29
Adverse event, serious fatal	2	-
Physician decision	1	2
Consent withdrawn by subject	1	6
Adverse event, non-fatal	6	3
Transferred to Ext Study MK-3543-017 (NCT06351631)	29	7
Subject decision	1	-
Sponsor decision	11	9
Disease Progression	1	2

Baseline characteristics

Reporting groups	
Reporting group title	Essential thrombocythemia (ET)
Reporting group description:	
Participants with ET received bomedemstat daily as an oral capsule. The daily dose of bomedemstat was titrated for each participant to a dose that reduced platelets to the target range associated with the participant's underlying MPN.	
Reporting group title	Myelofibrosis (MF)
Reporting group description:	
Participants with MF received bomedemstat daily as an oral capsule. The daily dose of bomedemstat was titrated for each participant to a dose that reduced platelets to the target range associated with the participant's underlying MPN.	

Reporting group values	Essential thrombocythemia (ET)	Myelofibrosis (MF)	Total
Number of subjects	52	29	81
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	24	13	37
From 65-84 years	26	16	42
85 years and over	2	0	2
Age Continuous Units: Years			
arithmetic mean	65.8	65.3	
standard deviation	± 11.01	± 9.68	-
Sex: Female, Male Units: Participants			
Female	29	14	43
Male	23	15	38
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	14	15	29
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	1	4
White	35	13	48
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	1	2

Not Hispanic or Latino	51	28	79
Unknown or Not Reported	0	0	0

Baseline Spleen Volume by Magnetic resonance imaging/computerized tomography (MRI/CT) in mL			
Baseline spleen volume was measured for myelofibrosis participants via MRI/CT scan in milliliters (mL).			
Units: mL			
median	9999	835.21	
full range (min-max)	9999 to 9999	98.88 to 3085.92	-
Baseline Platelet Counts in thousands per microliter (k/uL)			
Baseline platelet count measured in K/uL was obtained for both ET and MF participants.			
Units: K/uL			
arithmetic mean	380.4	190.5	
standard deviation	± 207.44	± 209.64	-

End points

End points reporting groups

Reporting group title	Essential thrombocythemia (ET)

Reporting group description:

Participants with ET received bomedemstat daily as an oral capsule. The daily dose of bomedemstat was titrated for each participant to a dose that reduced platelets to the target range associated with the participant's underlying MPN.

Reporting group title	Myelofibrosis (MF)

Reporting group description:

Participants with MF received bomedemstat daily as an oral capsule. The daily dose of bomedemstat was titrated for each participant to a dose that reduced platelets to the target range associated with the participant's underlying MPN.

Primary: Percentage of Participants who Experience an Adverse Event (AE)

End point title	Percentage of Participants who Experience an Adverse Event (AE)[1]

End point description:

An AE is any undesirable physical, psychological or behavioral effect experienced by a participant during participation in an investigational study, in conjunction with the use of the drug or biologic, whether or not product-related. This includes any clinically significant abnormalities in vital signs and lab values, untoward signs or symptoms experienced by the participant from the time of first dose with bomedemstat under this protocol until completion of the study. The analysis population includes all participants who received at least one dose of study intervention. The percentage of participants who experienced an AE is presented.

End point type	Primary

End point timeframe:

Up to ~32 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per protocol no statistical analysis was planned for this outcome measure.

End point values	Essential thrombocythemia (ET)	Myelofibrosis (MF)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	29		
Units: Percentage of Participants				
number (not applicable)	98.1	100.0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants who Discontinue Study Intervention Due to an AE

End point title	Percentage of Participants who Discontinue Study Intervention Due to an AE[2]

End point description:

An AE is any undesirable physical, psychological or behavioral effect experienced by a participant during participation in an investigational study, in conjunction with the use of the drug or biologic, whether or not product-related. This includes any clinically significant abnormalities in vital signs and lab values, untoward signs or symptoms experienced by the participant from the time of first dose with bomedemstat under this protocol until completion of the study. The analysis population includes all participants who received at least one dose of study intervention. The percentage of participants who discontinued study intervention due to an AE is presented.

End point type	Primary

End point timeframe:

Up to ~32 months

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per protocol no statistical analysis was planned for this outcome measure.

End point values	Essential thrombocythemia (ET)	Myelofibrosis (MF)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	29		
Units: Percentage of Participants				
number (not applicable)	15.4	10.3		

Statistical analyses

No statistical analyses for this end point

Primary: Mean Spleen Volume Reduction Based on Spleen Volume Measured by MRI in Participants with MF.

End point title	Mean Spleen Volume Reduction Based on Spleen Volume Measured by MRI in Participants with MF.[3]

End point description:

Mean Spleen volume reduction (mL) in participants with MF as measured by central laboratory imaging analysis of MRI (or CT where applicable) approximately every 48 weeks. The modified intent to treat (mITT) population included all participants who were enrolled in the study, received at least 1 dose of study intervention, and who had a nonmissing baseline and at least 1 nonmissing postbaseline efficacy assessment. Participants were analyzed according to treatment received in the study. Per protocol only participants with MF were analyzed for this outcome measure. The change in spleen volume from baseline is presented.

End point type	Primary

End point timeframe:

Baseline and Days 169, 339, 509, 679, 849 and 924

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per protocol no statistical analysis was planned for this outcome measure.

End point values	Essential thrombocythemia (ET)	Myelofibrosis (MF)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[4]	29		
Units: mL				
arithmetic mean (standard deviation)				

Day 169	()	-101.570 (± 92.6876)		
Day 339	()	-67.645 (± 249.0079)		
Day 509	()	-5.920 (± 143.1692)		
Day 679	()	-61.000 (± 396.2520)		
Day 849	()	-38.840 (± 9999)		
Day 924	()	80.575 (± 10.3308)		

Notes:

[4] - Per protocol only participants with MF were analyzed for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with ET who Achieve a Reduction of Platelet Counts to <= 400 k/uL (400 x 109/L) in the Absence of New Thromboembolic Events

End point title	Percentage of Participants with ET who Achieve a Reduction of Platelet Counts to <= 400 k/uL (400 x 109/L) in the Absence of New Thromboembolic Events[5]

End point description:

Blood samples were taken at designated time points to determine platelet count. The modified intent to treat (mITT) population included all participants who were enrolled in the study, received at least 1 dose of study intervention, and who had a nonmissing baseline and at least 1 nonmissing postbaseline efficacy assessment. Per protocol only participants with ET were analyzed for this outcome measure. Participants were analyzed according to treatment received in the study. Percentage of participants with ET who achieve a reduction of platelet counts to <= 400 k/uL (400 x 109/L) in the absence of new thromboembolic events is presented.

End point type	Primary

End point timeframe:

Baseline and Days 29, 57, 85, 113, 141, 169, 198, 226, 254, 282, 310, 338, 367, 395, 423, 451, 479, 507, 536, 564, 592, 620, and 648

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per protocol no statistical analysis was planned for this outcome measure.

End point values	Essential thrombocythemia (ET)	Myelofibrosis (MF)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	0[6]		
Units: Percentage of participants				
number (confidence interval 95%)				
Day 29	77.1 (62.7 to 88.0)	(to)		
Day 57	72.9 (58.2 to 84.7)	(to)		
Day 85	72.0 (57.5 to 83.8)	(to)		
Day 113	78.4 (64.7 to 88.7)	(to)		
Day 141	91.8 (80.4 to 97.7)	(to)		

Day 169	89.4 (76.9 to 96.5)	(to)		
Day 198	86.7 (73.2 to 94.9)	(to)		
Day 226	81.8 (67.3 to 91.8)	(to)		
Day 254	79.5 (64.7 to 90.2)	(to)		
Day 282	75.0 (59.7 to 86.8)	(to)		
Day 310	81.4 (66.6 to 91.6)	(to)		
Day 338	83.7 (69.3 to 93.2)	(to)		
Day 367	76.2 (60.5 to 87.9)	(to)		
Day 395	78.0 (62.4 to 89.4)	(to)		
Day 423	80.0 (64.4 to 90.9)	(to)		
Day 451	82.1 (66.5 to 92.5)	(to)		
Day 479	75.7 (58.8 to 88.2)	(to)		
Day 507	96.2 (80.4 to 99.9)	(to)		
Day 536	94.7 (74.0 to 99.9)	(to)		
Day 564	86.7 (59.5 to 98.3)	(to)		
Day 592	72.7 (39.0 to 94.0)	(to)		
Day 620	85.7 (42.1 to 99.6)	(to)		
Day 648	83.3 (35.9 to 99.6)	(to)		

Notes:

[6] - Per protocol only participants with ET were analyzed for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Death and adverse events up to ~32 months

Adverse event reporting additional description:

All-cause mortality was reported on all allocated participants. Serious and non-serious adverse events (AEs) were reported on all participants who received ≥1 dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Myelofibrosis (MF)

Reporting group description:

Participants with MF received bomedemstat daily as an oral capsule with dose-titration contingent on the titration assessment performed every 169 days. The daily dose of bomedemstat was titrated for each patient to a dose that reduces platelets to the underlying MPN's target range.

Reporting group title	Essential thrombocythemia (ET)

Reporting group description:

Participants with ET received bomedemstat daily as an oral capsule with dose-titration contingent on the titration assessment performed every 169 days. The daily dose of bomedemstat was titrated for each patient to a dose that reduces platelets to the underlying MPN's target range.

Serious adverse events	Myelofibrosis (MF)	Essential thrombocythemia (ET)	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 29 (41.38%)	19 / 52 (36.54%)	
number of deaths (all causes)	0	2	
number of deaths resulting from adverse events	0	2	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma multiforme			

subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypovolaemic shock			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphonia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood potassium increased			

subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	0 / 29 (0.00%)	2 / 52 (3.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Supraventricular tachycardia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wellens' syndrome			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	2 / 29 (6.90%)	3 / 52 (5.77%)	
occurrences causally related to treatment / all	1 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytosis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

Gastrointestinal disorders			
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival bleeding			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Portal vein thrombosis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 29 (3.45%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	0 / 29 (0.00%)	2 / 52 (3.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			

subjects affected / exposed	1 / 29 (3.45%)	3 / 52 (5.77%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 29 (3.45%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 29 (3.45%)	0 / 52 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Upper respiratory tract infection			
subjects affected / exposed	0 / 29 (0.00%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	1 / 29 (3.45%)	1 / 52 (1.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Myelofibrosis (MF)	Essential thrombocythemia (ET)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 29 (96.55%)	45 / 52 (86.54%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 29 (3.45%)	4 / 52 (7.69%)	
occurrences (all)	2	7	
Haematoma			
subjects affected / exposed	3 / 29 (10.34%)	3 / 52 (5.77%)	
occurrences (all)	3	5	
Hypotension			
subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	2	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 29 (10.34%)	2 / 52 (3.85%)	
occurrences (all)	5	2	
Fatigue			

subjects affected / exposed	2 / 29 (6.90%)	7 / 52 (13.46%)	
occurrences (all)	2	8	
Non-cardiac chest pain			
subjects affected / exposed	1 / 29 (3.45%)	3 / 52 (5.77%)	
occurrences (all)	1	3	
Oedema peripheral			
subjects affected / exposed	2 / 29 (6.90%)	3 / 52 (5.77%)	
occurrences (all)	3	4	
Peripheral swelling			
subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	2	1	
Pyrexia			
subjects affected / exposed	3 / 29 (10.34%)	2 / 52 (3.85%)	
occurrences (all)	3	2	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 29 (13.79%)	4 / 52 (7.69%)	
occurrences (all)	5	4	
Dyspnoea			
subjects affected / exposed	1 / 29 (3.45%)	5 / 52 (9.62%)	
occurrences (all)	1	6	
Epistaxis			
subjects affected / exposed	1 / 29 (3.45%)	4 / 52 (7.69%)	
occurrences (all)	2	4	
Pulmonary hypertension			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	2	0	
Investigations			
Urinary occult blood			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	2	0	
Alanine aminotransferase increased			

subjects affected / exposed	2 / 29 (6.90%)	2 / 52 (3.85%)	
occurrences (all)	2	2	
Blood creatinine increased			
subjects affected / exposed	0 / 29 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	8	
SARS-CoV-2 test positive			
subjects affected / exposed	4 / 29 (13.79%)	1 / 52 (1.92%)	
occurrences (all)	4	1	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	6 / 29 (20.69%)	4 / 52 (7.69%)	
occurrences (all)	13	4	
Fall			
subjects affected / exposed	1 / 29 (3.45%)	5 / 52 (9.62%)	
occurrences (all)	1	6	
Head injury			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	2	0	
Cardiac disorders			
Palpitations			
subjects affected / exposed	4 / 29 (13.79%)	2 / 52 (3.85%)	
occurrences (all)	5	2	
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 29 (13.79%)	8 / 52 (15.38%)	
occurrences (all)	4	8	
Dysgeusia			
subjects affected / exposed	4 / 29 (13.79%)	3 / 52 (5.77%)	
occurrences (all)	5	3	
Headache			
subjects affected / exposed	3 / 29 (10.34%)	7 / 52 (13.46%)	
occurrences (all)	3	7	
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	4 / 29 (13.79%)	2 / 52 (3.85%)	
occurrences (all)	4	2	

Anaemia			
subjects affected / exposed	7 / 29 (24.14%)	10 / 52 (19.23%)	
occurrences (all)	16	11	
Neutropenia			
subjects affected / exposed	2 / 29 (6.90%)	4 / 52 (7.69%)	
occurrences (all)	2	5	
Iron deficiency anaemia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	4	0	
Thrombocytosis			
subjects affected / exposed	0 / 29 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	5	
Thrombocytopenia			
subjects affected / exposed	12 / 29 (41.38%)	6 / 52 (11.54%)	
occurrences (all)	27	13	
Polycythaemia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	4	0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 29 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	3	
Eye disorders			
Blepharitis			
subjects affected / exposed	2 / 29 (6.90%)	2 / 52 (3.85%)	
occurrences (all)	2	2	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 29 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	3	
Abdominal pain			
subjects affected / exposed	0 / 29 (0.00%)	4 / 52 (7.69%)	
occurrences (all)	0	9	
Chronic gastritis			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	2	0	
Constipation			

subjects affected / exposed	3 / 29 (10.34%)	3 / 52 (5.77%)	
occurrences (all)	4	5	
Diarrhoea			
subjects affected / exposed	7 / 29 (24.14%)	5 / 52 (9.62%)	
occurrences (all)	8	10	
Vomiting			
subjects affected / exposed	0 / 29 (0.00%)	5 / 52 (9.62%)	
occurrences (all)	0	6	
Epigastric discomfort			
subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	2	1	
Gingival bleeding			
subjects affected / exposed	7 / 29 (24.14%)	3 / 52 (5.77%)	
occurrences (all)	14	3	
Haemorrhoids			
subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	2	1	
Mouth haemorrhage			
subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	3	1	
Mouth ulceration			
subjects affected / exposed	2 / 29 (6.90%)	3 / 52 (5.77%)	
occurrences (all)	2	3	
Nausea			
subjects affected / exposed	1 / 29 (3.45%)	6 / 52 (11.54%)	
occurrences (all)	1	6	
Rectal haemorrhage			
subjects affected / exposed	5 / 29 (17.24%)	0 / 52 (0.00%)	
occurrences (all)	10	0	
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 29 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	3	
Petechiae			
subjects affected / exposed	3 / 29 (10.34%)	0 / 52 (0.00%)	
occurrences (all)	3	0	

Pruritus			
subjects affected / exposed	3 / 29 (10.34%)	8 / 52 (15.38%)	
occurrences (all)	4	8	
Alopecia			
subjects affected / exposed	0 / 29 (0.00%)	5 / 52 (9.62%)	
occurrences (all)	0	6	
Ecchymosis			
subjects affected / exposed	4 / 29 (13.79%)	1 / 52 (1.92%)	
occurrences (all)	7	1	
Skin lesion			
subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	2	1	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 29 (10.34%)	5 / 52 (9.62%)	
occurrences (all)	4	5	
Arthritis			
subjects affected / exposed	2 / 29 (6.90%)	2 / 52 (3.85%)	
occurrences (all)	2	2	
Arthralgia			
subjects affected / exposed	14 / 29 (48.28%)	15 / 52 (28.85%)	
occurrences (all)	21	24	
Bone pain			
subjects affected / exposed	6 / 29 (20.69%)	0 / 52 (0.00%)	
occurrences (all)	7	0	
Pain in extremity			
subjects affected / exposed	1 / 29 (3.45%)	4 / 52 (7.69%)	
occurrences (all)	1	4	
Osteoarthritis			
subjects affected / exposed	1 / 29 (3.45%)	3 / 52 (5.77%)	
occurrences (all)	1	5	
Neck pain			
subjects affected / exposed	1 / 29 (3.45%)	3 / 52 (5.77%)	
occurrences (all)	1	3	
Myalgia			

subjects affected / exposed	0 / 29 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	4	
Muscle spasms			
subjects affected / exposed	2 / 29 (6.90%)	4 / 52 (7.69%)	
occurrences (all)	2	4	
Joint swelling			
subjects affected / exposed	4 / 29 (13.79%)	2 / 52 (3.85%)	
occurrences (all)	4	2	
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 29 (0.00%)	7 / 52 (13.46%)	
occurrences (all)	0	8	
Oral herpes			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	2	0	
Nasopharyngitis			
subjects affected / exposed	4 / 29 (13.79%)	4 / 52 (7.69%)	
occurrences (all)	4	4	
Cellulitis			
subjects affected / exposed	3 / 29 (10.34%)	3 / 52 (5.77%)	
occurrences (all)	3	3	
COVID-19			
subjects affected / exposed	11 / 29 (37.93%)	6 / 52 (11.54%)	
occurrences (all)	15	6	
Bronchitis			
subjects affected / exposed	2 / 29 (6.90%)	2 / 52 (3.85%)	
occurrences (all)	2	2	
Wound infection			
subjects affected / exposed	0 / 29 (0.00%)	3 / 52 (5.77%)	
occurrences (all)	0	3	
Upper respiratory tract infection			
subjects affected / exposed	4 / 29 (13.79%)	4 / 52 (7.69%)	
occurrences (all)	5	6	
Metabolism and nutrition disorders			
Iron deficiency			

subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	4	1	
Hyperuricaemia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 52 (0.00%)	
occurrences (all)	2	0	
Hyperkalaemia			
subjects affected / exposed	2 / 29 (6.90%)	1 / 52 (1.92%)	
occurrences (all)	4	1	
Decreased appetite			
subjects affected / exposed	4 / 29 (13.79%)	2 / 52 (3.85%)	
occurrences (all)	5	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 January 2024	Amendment 1 was made to address non-Merck protocol template. The rationale is further supported by acquisition of Imago BioSciences, Inc. by Merck & Co., Inc. This conversion resulted only in an entity name change and update to the address.
08 March 2024	Amendment 2 was made to address study extension where participants from this study were eligible to enroll in another bomedemstat extension study at any point before this study ended.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported