



Clinical trial results:

A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Single Agent Belantamab Mafodotin Compared to Pomalidomide plus Low-dose Dexamethasone (pom/dex) in Participants with Relapsed/Refractory Multiple Myeloma (RRMM) (DREAMM 3)

Summary

EudraCT number	2018-004252-38
Trial protocol	GB NL DE FR ES BE HU GR PL BG IT
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	27 September 2023
First version publication date	27 September 2023

Trial information

Trial identification

Sponsor protocol code	207495
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04162210
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 GreatWest Road, Brentford,Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.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	Interim
Date of interim/final analysis	04 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 September 2022
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy with belantamab mafodotin vs pomalidomide plus low dose dexamethasone (pom/dex) in participants with relapsed/refractory multiple myeloma (RRMM)

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 April 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 32
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Brazil: 37
Country: Number of subjects enrolled	Bulgaria: 16
Country: Number of subjects enrolled	China: 33
Country: Number of subjects enrolled	France: 8
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Greece: 39
Country: Number of subjects enrolled	Hungary: 26
Country: Number of subjects enrolled	Italy: 16
Country: Number of subjects enrolled	Japan: 17
Country: Number of subjects enrolled	Korea, Republic of: 14
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Poland: 11
Country: Number of subjects enrolled	Russian Federation: 32
Country: Number of subjects enrolled	Spain: 6
Country: Number of subjects enrolled	United Kingdom: 18
Country: Number of subjects enrolled	United States: 10
Worldwide total number of subjects	325
EEA total number of subjects	132

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
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)	124
From 65 to 84 years	197
85 years and over	4

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The results presented are based on the primary analysis (and includes data up to a maximum of 27 months). Data collection is still ongoing and additional results will be provided after study completion.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Belantamab mafodotin

Arm description:

Participants with relapsed/refractory multiple myeloma (RRMM) received at least 30 minutes intravenous infusion of 2.5 milligram/kilogram (mg/kg) belantamab mafodotin on day 1 of each 21-day cycle up to approximately 23 months.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Participants with relapsed/refractory multiple myeloma (RRMM) received intravenous solution of 2.5 milligram/kilogram (mg/kg) belantamab mafodotin as single agent on day 1 of every 21-day cycle up to approximately 23 months.

Arm title	Pomalidomide plus Dexamethasone
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Arm description:

Participants with RRMM received 4 mg pomalidomide capsule daily on Days 1 to 21 of each 28-day cycle, along with 40 mg or at lower 20 mg (for participants >75 years of age) dose of dexamethasone tablet once weekly (Days 1, 8, 15 and 22) up to approximately 24 months.

Arm type	Active comparator
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants with RRMM received 4 mg pomalidomide capsule daily on Days 1 to 21 of each 28-day cycle, with 40 mg or at lower 20 mg dose of dexamethasone tablet once weekly (Days 1, 8, 15 and 22) up to approximately 24 months.

Investigational medicinal product name	Pomalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants with RRMM received 4 mg pomalidomide capsule daily on Days 1 to 21 of each 28-day cycle, with 40 mg or at lower 20 mg dose of dexamethasone tablet once weekly (Days 1, 8, 15 and 22) up to approximately 24 months.

Number of subjects in period 1	Belantamab mafodotin	Pomalidomide plus Dexamethasone
Started	218	107
Safety Population	217	102
Completed	84	38
Not completed	134	69
Consent withdrawn by subject	17	9
Ongoing	113	59
Lost to follow-up	4	1

Baseline characteristics

Reporting groups

Reporting group title	Belantamab mafodotin
Reporting group description: Participants with relapsed/refractory multiple myeloma (RRMM) received at least 30 minutes intravenous infusion of 2.5 milligram/kilogram (mg/kg) belantamab mafodotin on day 1 of each 21-day cycle up to approximately 23 months.	
Reporting group title	Pomalidomide plus Dexamethasone
Reporting group description: Participants with RRMM received 4 mg pomalidomide capsule daily on Days 1 to 21 of each 28-day cycle, along with 40 mg or at lower 20 mg (for participants >75 years of age) dose of dexamethasone tablet once weekly (Days 1, 8, 15 and 22) up to approximately 24 months.	

Reporting group values	Belantamab mafodotin	Pomalidomide plus Dexamethasone	Total
Number of subjects	218	107	325
Age categorical Units: Subjects			
<65 years	81	43	124
>=65 to <75 years	90	41	131
>=75 years	47	23	70
Sex: Female, Male Units: Participants			
Female	100	41	141
Male	118	66	184
Race/Ethnicity, Customized Units: Subjects			
Asian	47	19	66
Black Or African American	3	1	4
White	162	84	246
Not Reported	6	3	9
Age, Continuous Units: YEARS			
arithmetic mean	66.3	66.6	
standard deviation	± 9.67	± 9.68	-

End points

End points reporting groups

Reporting group title	Belantamab mafodotin
Reporting group description: Participants with relapsed/refractory multiple myeloma (RRMM) received at least 30 minutes intravenous infusion of 2.5 milligram/kilogram (mg/kg) belantamab mafodotin on day 1 of each 21-day cycle up to approximately 23 months.	
Reporting group title	Pomalidomide plus Dexamethasone
Reporting group description: Participants with RRMM received 4 mg pomalidomide capsule daily on Days 1 to 21 of each 28-day cycle, along with 40 mg or at lower 20 mg (for participants >75 years of age) dose of dexamethasone tablet once weekly (Days 1, 8, 15 and 22) up to approximately 24 months.	

Primary: Progression-free survival (PFS) based on investigator-assessed response as per international myeloma working group (IMWG)

End point title	Progression-free survival (PFS) based on investigator-assessed response as per international myeloma working group (IMWG)
End point description: PFS is time from randomization until earliest date of progressive disease (PD), or death due to any cause per investigator-assessed response per IMWG. PD is $\geq 25\%$ increase from nadir in any of following: serum M-protein (absolute increase ≥ 0.5 gram per deciliter [g/dL]), urine M-protein (absolute increase ≥ 200 mg/24hr), difference between involved/uninvolved FLC levels (absolute increase > 10 mg/dL) in patients without measurable serum and urine M-protein levels, or bone marrow plasma-cell percentage irrespective of baseline status (absolute increase $\geq 10\%$) in patients without measurable serum and urine M-protein levels and without measurable involved FLC levels; appearance of new lesion, $\geq 50\%$ increase in longest diameter of a lesion previously measured > 1 cm in short axis, or $\geq 50\%$ increase from nadir in sum of products of two longest perpendicular diameters of more than 1 lesion; $\geq 50\%$ increase in circulating plasma cells (minimum of 200 cells/microliter) if this is only measure of disease.	
End point type	Primary
End point timeframe: Up to 27 months	

End point values	Belantamab mafodotin	Pomalidomide plus Dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	218	107		
Units: Months				
median (confidence interval 95%)	11.2 (6.4 to 14.5)	7.0 (4.6 to 10.6)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: HR was estimated using the Cox Proportional Hazards. HR stratified log-rank test were adjusted for	

previous treatment with anti-CD38, international staging system (ISS) staging and number of prior lines of therapy.

Comparison groups	Belantamab mafodotin v Pomalidomide plus Dexamethasone
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.558 ^[1]
Method	Logrank
Parameter estimate	Stratified Hazard Ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.47

Notes:

[1] - One-sided p-value from stratified log-rank test were adjusted for previous treatment with anti-CD38, ISS staging and number of prior lines of therapy.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All cause deaths, non-serious adverse events (Non-SAEs) and serious adverse events (SAEs) were collected maximum up to 27 months. Data collection is still ongoing and additional results will be provided after study completion.

Adverse event reporting additional description:

All cause deaths, SAEs and non-serious adverse events were reported for the safety population that included all randomized participants who received at least 1 dose of any study intervention.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Pomalidomide plus Dexamethasone
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Reporting group description:

Participants with RRMM received 4 mg pomalidomide capsule daily on Days 1 to 21 of each 28-day cycle, along with 40 mg or at lower 20 mg (for participants >75 years of age) dose of dexamethasone tablet once weekly (Days 1, 8, 15 and 22) up to approximately 24 months.

Reporting group title	Belantamab mafodotin
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Reporting group description:

Participants with relapsed/refractory multiple myeloma (RRMM) received at least 30 minutes intravenous infusion of 2.5 milligram/kilogram (mg/kg) belantamab mafodotin on day 1 of each 21-day cycle up to approximately 23 months.

Serious adverse events	Pomalidomide plus Dexamethasone	Belantamab mafodotin	
Total subjects affected by serious adverse events			
subjects affected / exposed	40 / 102 (39.22%)	94 / 217 (43.32%)	
number of deaths (all causes)	38	83	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone neoplasm			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 102 (0.98%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Plasma cell myeloma			

subjects affected / exposed	0 / 102 (0.00%)	3 / 217 (1.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Bowen's disease			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord neoplasm			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Shock haemorrhagic			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			

subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 102 (0.00%)	7 / 217 (3.23%)	
occurrences causally related to treatment / all	0 / 0	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Loss of personal independence in daily activities			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			

subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device extrusion			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 102 (0.00%)	4 / 217 (1.84%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	1 / 102 (0.98%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (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			
Femur fracture			

subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 102 (0.00%)	3 / 217 (1.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 102 (0.00%)	4 / 217 (1.84%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	1 / 102 (0.98%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Road traffic accident			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hip fracture			
subjects affected / exposed	1 / 102 (0.98%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dislocation of vertebra			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			

subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angina pectoris			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 102 (0.98%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac arrest			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorders			

Spinal cord compression			
subjects affected / exposed	0 / 102 (0.00%)	3 / 217 (1.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transient ischaemic attack			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral motor neuropathy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular pain			

subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperammonaemic encephalopathy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
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			
Thrombocytopenia			
subjects affected / exposed	1 / 102 (0.98%)	8 / 217 (3.69%)	
occurrences causally related to treatment / all	1 / 1	5 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	1 / 102 (0.98%)	5 / 217 (2.30%)	
occurrences causally related to treatment / all	1 / 1	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 102 (0.98%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	5 / 102 (4.90%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	4 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelosuppression			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal compartment syndrome			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vomiting			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			

subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			

subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
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			
Pathological fracture			
subjects affected / exposed	0 / 102 (0.00%)	3 / 217 (1.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 102 (0.98%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis of jaw			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			

subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	8 / 102 (7.84%)	6 / 217 (2.76%)	
occurrences causally related to treatment / all	6 / 10	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 1	
COVID-19			
subjects affected / exposed	3 / 102 (2.94%)	5 / 217 (2.30%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
Urinary tract infection			
subjects affected / exposed	0 / 102 (0.00%)	3 / 217 (1.38%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 102 (0.00%)	3 / 217 (1.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	3 / 102 (2.94%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	2 / 3	0 / 2	
deaths causally related to treatment / all	1 / 2	0 / 2	
Osteomyelitis			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	5 / 102 (4.90%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arthritis infective			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous bacterial peritonitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	1 / 102 (0.98%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pseudomembranous colitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 217 (0.46%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (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 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			

subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary nocardiosis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	1 / 102 (0.98%)	0 / 217 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 102 (0.00%)	2 / 217 (0.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Pomalidomide plus Dexamethasone	Belantamab mafodotin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	88 / 102 (86.27%)	200 / 217 (92.17%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 102 (1.96%)	13 / 217 (5.99%)	
occurrences (all)	2	13	
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	10 / 102 (9.80%)	6 / 217 (2.76%)	
occurrences (all)	12	7	

Chills			
subjects affected / exposed	0 / 102 (0.00%)	13 / 217 (5.99%)	
occurrences (all)	0	16	
Fatigue			
subjects affected / exposed	15 / 102 (14.71%)	18 / 217 (8.29%)	
occurrences (all)	15	19	
Pyrexia			
subjects affected / exposed	9 / 102 (8.82%)	34 / 217 (15.67%)	
occurrences (all)	11	47	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	7 / 102 (6.86%)	9 / 217 (4.15%)	
occurrences (all)	13	9	
Epistaxis			
subjects affected / exposed	2 / 102 (1.96%)	11 / 217 (5.07%)	
occurrences (all)	2	12	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 102 (4.90%)	30 / 217 (13.82%)	
occurrences (all)	8	32	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 102 (0.00%)	33 / 217 (15.21%)	
occurrences (all)	0	37	
Neutrophil count decreased			
subjects affected / exposed	14 / 102 (13.73%)	17 / 217 (7.83%)	
occurrences (all)	34	35	
Gamma-glutamyltransferase increased			
subjects affected / exposed	5 / 102 (4.90%)	22 / 217 (10.14%)	
occurrences (all)	6	24	
Platelet count decreased			
subjects affected / exposed	12 / 102 (11.76%)	27 / 217 (12.44%)	
occurrences (all)	19	32	
Alanine aminotransferase increased			

subjects affected / exposed	8 / 102 (7.84%)	14 / 217 (6.45%)	
occurrences (all)	17	16	
Lymphocyte count decreased			
subjects affected / exposed	6 / 102 (5.88%)	8 / 217 (3.69%)	
occurrences (all)	9	15	
Blood creatinine increased			
subjects affected / exposed	6 / 102 (5.88%)	10 / 217 (4.61%)	
occurrences (all)	7	11	
White blood cell count decreased			
subjects affected / exposed	9 / 102 (8.82%)	12 / 217 (5.53%)	
occurrences (all)	21	19	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 102 (0.00%)	15 / 217 (6.91%)	
occurrences (all)	0	25	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	30 / 102 (29.41%)	61 / 217 (28.11%)	
occurrences (all)	37	78	
Neutropenia			
subjects affected / exposed	39 / 102 (38.24%)	24 / 217 (11.06%)	
occurrences (all)	86	47	
Leukopenia			
subjects affected / exposed	9 / 102 (8.82%)	7 / 217 (3.23%)	
occurrences (all)	19	8	
Thrombocytopenia			
subjects affected / exposed	31 / 102 (30.39%)	70 / 217 (32.26%)	
occurrences (all)	61	98	
Lymphopenia			
subjects affected / exposed	7 / 102 (6.86%)	5 / 217 (2.30%)	
occurrences (all)	24	8	
Eye disorders			
Eye irritation			
subjects affected / exposed	1 / 102 (0.98%)	50 / 217 (23.04%)	
occurrences (all)	2	87	
Visual acuity reduced			

subjects affected / exposed	1 / 102 (0.98%)	41 / 217 (18.89%)	
occurrences (all)	1	97	
Eye pain			
subjects affected / exposed	0 / 102 (0.00%)	35 / 217 (16.13%)	
occurrences (all)	0	54	
Keratopathy			
subjects affected / exposed	1 / 102 (0.98%)	26 / 217 (11.98%)	
occurrences (all)	1	29	
Punctate keratitis			
subjects affected / exposed	0 / 102 (0.00%)	23 / 217 (10.60%)	
occurrences (all)	0	44	
Visual impairment			
subjects affected / exposed	0 / 102 (0.00%)	13 / 217 (5.99%)	
occurrences (all)	0	25	
Cataract			
subjects affected / exposed	5 / 102 (4.90%)	12 / 217 (5.53%)	
occurrences (all)	6	14	
Keratitis			
subjects affected / exposed	0 / 102 (0.00%)	12 / 217 (5.53%)	
occurrences (all)	0	14	
Foreign body sensation in eyes			
subjects affected / exposed	2 / 102 (1.96%)	57 / 217 (26.27%)	
occurrences (all)	2	129	
Dry eye			
subjects affected / exposed	2 / 102 (1.96%)	61 / 217 (28.11%)	
occurrences (all)	2	116	
Vision blurred			
subjects affected / exposed	2 / 102 (1.96%)	86 / 217 (39.63%)	
occurrences (all)	2	172	
Photophobia			
subjects affected / exposed	1 / 102 (0.98%)	46 / 217 (21.20%)	
occurrences (all)	1	64	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 102 (0.98%)	16 / 217 (7.37%)	
occurrences (all)	1	22	

Diarrhoea subjects affected / exposed occurrences (all)	11 / 102 (10.78%) 14	22 / 217 (10.14%) 27	
Nausea subjects affected / exposed occurrences (all)	4 / 102 (3.92%) 8	25 / 217 (11.52%) 32	
Constipation subjects affected / exposed occurrences (all)	9 / 102 (8.82%) 10	12 / 217 (5.53%) 12	
Hepatobiliary disorders Hepatic function abnormal subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0	11 / 217 (5.07%) 14	
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	6 / 102 (5.88%) 6	4 / 217 (1.84%) 4	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	9 / 102 (8.82%) 9 10 / 102 (9.80%) 11	20 / 217 (9.22%) 22 13 / 217 (5.99%) 15	
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all) COVID-19 subjects affected / exposed occurrences (all)	2 / 102 (1.96%) 2 9 / 102 (8.82%) 9	12 / 217 (5.53%) 17 24 / 217 (11.06%) 24	
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all) Hypokalaemia	6 / 102 (5.88%) 7	6 / 217 (2.76%) 6	

subjects affected / exposed	3 / 102 (2.94%)	14 / 217 (6.45%)	
occurrences (all)	4	16	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 October 2020	This protocol amendment was implemented following regulatory agency input and a review of data from the Phase 2 DREAMM-2 study. This amendment addressed specifically the rules for dose modification.
20 September 2021	This protocol amendment included an update to the planned PFS futility interim analysis.
21 October 2021	The protocol amendment increased the global enrollment cap (limit) for participants who have received ≤ 3 prior lines from 40% to 55%.
20 April 2022	This protocol amendment was issued after the timeframe for study completion was re-estimated based on the current accrual rate of PFS events, which were slower than originally anticipated.
07 September 2022	Amendment included updates to the method for the primary analysis of efficacy endpoints from being based on algorithm-derived confirmed response and dates per International Myeloma Working Group (IMWG).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported