Clinical trial results:
A Phase I/II Single Arm Open-Label Study to Explore Safety and Clinical Activity of GSK2857916 Administered in Combination with Pembrolizumab in Subjects with Relapsed/Refractory Multiple Myeloma (DREAMM 4)

Summary

EudraCT number	2018-002816-29
Trial protocol	DE ES
Global end of trial date	14 June 2023

Results information

Result version number	v3
This version publication date	24 December 2023
First version publication date	01 November 2022
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	205207

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GlaxoSmithKline, GSK Response Center, 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	Final
Date of interim/final analysis	14 September 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the recommended Phase 2 dose (RP2D) of belantamab mafodotin in combination with pembrolizumab, and to evaluate safety and clinical activity of the combination in subjects with RRMM.

Protection of trial subjects:

Not Applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 March 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	36 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 12
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	United States: 17
Worldwide total number of subjects	41
EEA total number of subjects	12

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)	20

From 65 to 84 years	21
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study consisted of two phases - Main Study Phase and Post Analysis Continued Treatment (PACT) Phase. In PACT phase those participants still benefiting from drug continued to receive study drug until discontinued or withdrawn from the study.

Pre-assignment

Screening details:

Total of 41 participants were enrolled in this study.

Period 1

Period 1 title	Main Study Phase (Day 1 to Week 178)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation

Arm description:

Participants were administered 2.5 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

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

Dosage and administration details:

Belantamab mafodotin was administered as a 2.5 mg/kg dose in combination with 200 mg of pembrolizumab via IV infusion

Arm title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation

Arm description:

Participants were administered with 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.

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

Dosage and administration details:

Belantamab mafodotin was administered as a 3.4 mg/kg dose in combination with 200 mg of pembrolizumab via IV infusion

Arm title	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg

Arm description:

Participants were administered belantamab mafodotin with recommended phase 2 dose (RP2D) of 2.5 mg/kg in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.

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

Dosage and administration details:

Belantamab mafodotin was administered as a 2.5 mg/kg dose in combination with 200 mg of pembrolizumab via IV infusion

Number of subjects in period 1	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg Escalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg
Started	6	7	28
Completed	3	4	19
Not completed	3	3	9
Consent withdrawn by subject	3	2	8
Physician decision	-	-	1
Lost to follow-up	-	1	-

Period 2

Period 2 title	PACT Phase (Week 178 to Week 221)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	PACT Phase- Belantamab mafodotin2.5mg/kg+Pembrolizumab 200 mg

Arm description:

Participants who completed approximately 178 weeks of treatment of 2.5 mg/kg belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion had the opportunity to continue receiving belantamab mafodotin in the PACT phase up to approximately 221 weeks.

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

Dosage and administration details:

Belantamab mafodotin was administered as a 2.5 mg/kg dose in combination with 200 mg of pembrolizumab via IV infusion

Number of subjects in period 2[1]	PACT Phase-Belantamab mafodotin2.5mg/kg +Pembrolizumab 200 mg
Started	2
Completed	1
Not completed	1
Consent withdrawn by subject	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants who completed approximately 175 weeks of treatment of 2.5 mg/kg belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion had the opportunity to continue receiving belantamab mafodotin in the PACT phase up to approximately 229 weeks.

Baseline characteristics

Reporting groups	
Reporting group title	Part1:BelantamabMafodotin2.5mg/kg+PembrolizumabEscalation
Reporting group description:	
Participants were administered 2.5 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.	
Reporting group title	Part1:BelantamabMafodotin3.4mg/kg+PembrolizumabEscalation
Reporting group description:	
Participants were administered with 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.	
Reporting group title	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg
Reporting group description:	
Participants were administered belantamab mafodotin with recommended phase 2 dose (RP2D) of 2.5 mg/kg in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.	

Reporting group values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg Escalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg
Number of subjects	6	7	28
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)	2	1	17
From 65-84 years	4	6	11
85 years and over	0	0	0
Sex: Female, Male Units: Participants			
Female	5	4	10
Male	1	3	18
Race/Ethnicity, Customized Units: Subjects			
Asian	0	0	1
Black OR African American	1	2	4
White	5	5	23
Age, Continuous Units: YEARS			
arithmetic mean	66.8	67.7	61.5

standard deviation	± 12.09	± 9.21	± 9.41

Reporting group values	Total		
Number of subjects	41		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	20		
From 65-84 years	21		
85 years and over	0		
Sex: Female, Male Units: Participants			
Female	19		
Male	22		
Race/Ethnicity, Customized Units: Subjects			
Asian	1		
Black OR African American	7		
White	33		
Age, Continuous Units: YEARS			
arithmetic mean			
standard deviation	-		

Subject analysis sets

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of

pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Reporting group values	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Number of subjects	7	4	5
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Sex: Female, Male Units: Participants			
Female Male			
Race/Ethnicity, Customized Units: Subjects			
Asian Black OR African American White			
Age, Continuous Units: YEARS			
arithmetic mean	43	13.350	1.0966
standard deviation	±	±	± 40.9

Reporting group values	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Number of subjects	6		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Sex: Female, Male Units: Participants			
Female Male			
Race/Ethnicity, Customized Units: Subjects			
Asian Black OR African American White			
Age, Continuous Units: YEARS arithmetic mean standard deviation	 ±		

End points

End points reporting groups

Reporting group title	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation

Reporting group description:

Participants were administered 2.5 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Reporting group title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation

Reporting group description:

Participants were administered with 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.

Reporting group title	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg

Reporting group description:

Participants were administered belantamab mafodotin with recommended phase 2 dose (RP2D) of 2.5 mg/kg in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.

Reporting group title	PACT Phase- Belantamab mafodotin2.5mg/kg+Pembrolizumab 200 mg

Reporting group description:

Participants who completed approximately 178 weeks of treatment of 2.5 mg/kg belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion had the opportunity to continue receiving belantamab mafodotin in the PACT phase up to approximately 221 weeks.

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Subject analysis set title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants were administered 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Primary: Part 1 - Number of participants with adverse events (AEs) and serious adverse events (SAEs) - All Treated Population

End point title	Part 1 - Number of participants with adverse events (AEs) and serious adverse events (SAEs) - All Treated Population[1][2]

End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations which involve medical or scientific judgment or is associated with liver injury and impaired liver function.

End point type	Primary

End point timeframe:

Up to approximately 31 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
AEs	6	7		
SAEs	4	5		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with dose limiting toxicities (DLTs) - All Treated Population

End point title	Part 1 - Number of participants with dose limiting toxicities (DLTs) - All Treated Population[3][4]

End point description:

DLT is an AE that is considered by the investigator to be clinically relevant and attributed to the study therapy during the 21day DLT period and meets at least one of the DLT criteria: any Grade 4 and 3 non-hematologic toxicity, any Grade 3 or greater non-hematologic laboratory value, hematologic toxicity lasting >=7 days, except Grade 4 thrombocytopenia of any duration or Grade3 thrombocytopenia associated with clinically significant bleeding. Grade3 or greater febrile neutropenia lasting >48 hours (h) despite adequate treatment, Nephrotoxicity requiring dialysis, Liver toxicity, prolonged delay (>14 days) in initiating Cycle 2 due to any treatment (pembrolizumab or GSK2857916) related toxicity, any treatment-related toxicity that causes discontinuation of treatment during Cycle 1, any other toxicity considered to be dose-limiting that occurs beyond 21 days and any other event which in the judgment of the investigator and GlaxoSmithKline Medical Monitor is considered to be a DLT.

End point type	Primary

End point timeframe:

Up to 21 days

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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with worst-case grade change from baseline in hematology parameters - All Treated Population

End point title	Part 1 - Number of participants with worst-case grade change from baseline in hematology parameters - All Treated Population[5][6]

End point description:

Blood samples were collected for the analysis of following hematology parameters: hemoglobin, White blood cells (WBC) count, lymphocytes, neutrophils and platelet count. The laboratory parameters were graded according to National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 4.03. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life-threatening consequences. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Any worst-case post baseline increase in grade along with any increase to a maximum grade of 3 and a maximum grade of 4 are presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 31 months

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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
Hemoglobin Decreased (Anemia), Any Grade Increase	4	2		
Hemoglobin Decreased (Anemia), Increase to Grade 3	3	1		
Hemoglobin Decreased (Anemia), Increase to Grade 4	0	0		
Hemoglobin Increased, Any Grade Increase	0	0		
Hemoglobin Increased, Increase to Grade 3	0	0		
Hemoglobin Increased, Increase to Grade 4	0	0		
WBC Increased (Leukocytosis), Any Grade Increase	0	0		
WBC Increased (Leukocytosis), Increase to Grade 3	0	0		
WBC Increased (Leukocytosis), Increase to Grade 4	0	0		
WBC Decreased, Any Grade Increase	3	3		
WBC Decreased, Increase to Grade 3	1	1		
WBC Decreased, Increase to Grade 4	0	0		
Lymphocyte Decreased, Any Grade Increase	4	1		
Lymphocyte Decreased, Increase to Grade 3	1	1		
Lymphocyte Decreased, Increase to Grade 4	1	0		
Lymphocyte Increased, Any Grade Increase	0	1		
Lymphocyte Increased, Increase to Grade 3	0	0		
Lymphocyte Increased, Increase to Grade 4	0	0		
Neutrophil Decreased, Any Grade Increase	5	2		
Neutrophil Decreased, Increase to Grade 3	2	1		
Neutrophil Decreased, Increase to Grade 4	0	1		
Platelet Decreased, Any Grade Increase	5	5		
Platelet Decreased, Increase to Grade 3	3	3		
Platelet Decreased, Increase to Grade 4	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with worst-case change post-baseline in hematology parameters - All Treated Population

End point title	Part 1 - Number of participants with worst-case change post-baseline in hematology parameters - All Treated Population[7][8]

End point description:

Blood samples were collected for the analysis of following hematology parameters: basophils, eosinophils, mean corpuscular hemoglobin concentration (MCHC), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), erythrocytes, hematocrit, monocytes, neutrophils and reticulocyte. The summaries of worst-case change from baseline with respect to normal range was analyzed for only those laboratory tests that were not gradable by CTCAE version 4.03. The number of participants with decreases to low from baseline, changes to normal or no changes from baseline, and increases to high values have been presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 31 months

Notes:

[7] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
Basophils, Decrease to Low	0	0		
Basophils, Change to Normal or No Change	6	6		
Basophils, Increase to High	0	0		
Eosinophils, Decrease to Low	2	1		
Eosinophils, Change to Normal or No Change	4	6		
Eosinophils, Increase to High	0	0		
MCHC, Decrease to Low	0	1		
MCHC, Change to Normal or No Change	6	4		
MCHC, Increase to High	0	2		
MCH, Decrease to Low	2	0		
MCH, Change to Normal or No Change	3	5		
MCH, Increase to High	0	1		
MCV, Decrease to Low	1	0		
MCV, Change to Normal or No Change	5	6		
MCV, Increase to High	0	1		
Erythrocytes, Decrease to Low	0	1		
Erythrocytes, Change to Normal or No Change	6	6		
Erythrocytes, Increase to High	0	0		
Hematocrit, Decrease to Low	0	0		
Hematocrit, Change to Normal or No Change	5	7		

Hematocrit, Increase to High	1	0		
Monocytes, Decrease to Low	0	0		
Monocytes, Change to Normal or No Change	3	4		
Monocytes, Increase to High	3	3		
Reticulocyte, Decrease to Low	4	0		
Reticulocyte, Change to Normal or No Change	0	4		
Reticulocyte, Increase to High	4	2		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with worst-case grade change from baseline in lab chemistry parameters - All Treated Population

End point title	Part 1 - Number of participants with worst-case grade change from baseline in lab chemistry parameters - All Treated Population[9][10]

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: glucose, alanine aminotransferase (ALT), albumin, alkaline phosphatase, aspartate aminotransferase (AST), blood bilirubin, calcium, creatine kinase (CPK), creatinine, gamma glutamyl transferase (GGT), magnesium, phosphate, potassium and sodium. Laboratory parameters were graded according to NCI-CTCAE version 4.03. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life-threatening consequences. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Any worst case post baseline increase in grade along with any increase to a maximum grade of 3 and a maximum grade of 4 are presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 31 months

Notes:

[9] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:Belantamab Mafodotin2.5 mg/kg+Pembrolizumab200mg Escalation	Part1:Belantamab Mafodotin3.4 mg/kg+Pembrolizumab200mg Escalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
Glucose Increased, Any Grade Increase	0	0		
Glucose Increased,Increase to Grade3	0	0		
Glucose Increased,Increase to Grade4	0	0		

GlucoseDecreased(Hypoglycemia), Any Grade Increase	1	0		
Glucose Decreased,Increase to Grade 3	0	0		
Glucose Decreased,Increase to Grade 4	0	0		
ALT Increased, Any Grade Increase	3	0		
ALT Increased, Increase to Grade 3	0	0		
ALT Increased, Increase to Grade 4	0	0		
AlbuminDecreased,AnyGradeIncrease	1	4		
AlbuminDecreased,Increase to 3	0	0		
AlbuminDecreased,Increase to 4	0	0		
Alkalinphosphatase Increased, Any Grade Increase	3	2		
Alkalinephosphatase Increased, Increase to Grade 3	0	0		
Alkalinephosphatase Increased, Increase to Grade 4	0	0		
AST Increased, Any Grade Increase	5	5		
AST Increased, Increase to Grade 3	0	0		
AST Increased, Increase to Grade 4	0	0		
Blood bilirubin Increased, Any Grade Increase	0	1		
Blood bilirubin Increased, Increase to Grade 3	0	0		
Blood bilirubin Increased, Increase to Grade 4	0	0		
Calcium Increased,Any Grade Increase	2	1		
Calcium Increased,Increase to 3	0	0		
Calcium Increased,Increase to 4	0	0		
Calcium Decreased, Any Grade Increase	2	0		
Calcium Decreased, Increase to Grade 3	0	0		
Calcium Decreased, Increase to Grade 4	0	0		
CPK Increased, Any Grade Increase	1	2		
CPK Increased, Increase to Grade 3	0	0		
CPK Increased, Increase to Grade 4	0	0		
Creatinine Increased, Any Grade Increase	2	1		
Creatinine Increased, Increase to Grade 3	0	0		
Creatinine Increased, Increase to Grade 4	0	0		
GGT Increased, Any Grade Increase	3	2		
GGT Increased, Increase to Grade 3	0	0		
GGT Increased, Increase to Grade 4	0	0		
Magnesium Increase,Any Grade Increase	0	0		
Magnesium Increased, Increase to Grade 3	0	0		
Magnesium Increased, Increase to Grade 4	0	0		
Magnesium Decreased, Any Grade Increase	2	2		
Magnesium Decreased, Increase to Grade 3	0	0		
Magnesium Decreased, Increase to Grade 4	0	0		
Phosphate Decreased, Any Grade Increase	2	0		

Phosphate Decreased, Increase to Grade 3	0	0		
Phosphate Decreased, Increase to Grade 4	0	0		
Potassium Increased, Any Grade Increase	0	0		
Potassium Increased, Increase to Grade 3	0	0		
Potassium Increased, Increase to Grade 4	0	0		
Potassium Decreased, Any Grade Increase	2	2		
Potassium Decreased, Increase to Grade 3	0	1		
Potassium Decreased, Increase to Grade 4	0	0		
Sodium Increased, Any Grade Increase	0	0		
Sodium Increased, Increase to Grade 3	0	0		
Sodium Increased, Increase to Grade 4	0	0		
Sodium Decreased, Any Grade Increase	1	3		
Sodium Decreased, Increase to Grade 3	0	2		
Sodium Decreased, Increase to Grade 4	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with worst-case change post-baseline in lab chemistry parameters - All Treated Population

End point title	Part 1 - Number of participants with worst-case change post-baseline in lab chemistry parameters - All Treated Population[11][12]

End point description:

Blood samples were collected for the analysis of following chemistry parameters: calcium, carbon dioxide, chloride, direct bilirubin, protein, thyrotropin (TSH), thyroxine (T4) and triiodothyronine (T3). The summaries of worst case change from baseline with respect to normal range was analyzed for only those laboratory tests that were not gradable by CTCAE version 4.03. The number of participants with decreases to low from baseline, changes to normal or no changes from baseline, and increases to high values have been presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to 31 months

Notes:

[11] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
Calcium, Decrease to Low	1	2		
Calcium, Change to Normal or No Change	4	4		
Calcium, Increase to High	1	1		
Carbon dioxide, Decrease to Low	2	1		
Carbon dioxide, Change to Normal or No Change	3	4		
Carbon dioxide, Increase to High	1	1		
Chloride, Decrease to Low	1	2		
Chloride, Change to Normal or No Change	4	4		
Chloride, Increase to High	1	1		
Direct bilirubin, Decrease to Low	0	0		
Direct bilirubin, Change to Normal or No Change	4	5		
Direct bilirubin, Increase to High	1	1		
Protein, Decrease to Low	2	3		
Protein, Change to Normal or No Change	3	4		
Protein, Increase to High	1	1		
TSH, Decrease to Low	0	0		
TSH, Change to Normal or No Change	3	4		
TSH, Increase to High	3	2		
T4, Decrease to Low	1	0		
T4, Change to Normal or No Change	5	6		
T4, Increase to High	1	0		
T3, Decrease to Low	1	1		
T3, Change to Normal or No Change	1	0		
T3, Increase to High	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with worst-case grade change from baseline in vital signs: diastolic blood pressure (DBP) and systolic blood pressure (SBP) - All Treated Population

End point title	Part 1 - Number of participants with worst-case grade change from baseline in vital signs: diastolic blood pressure (DBP) and systolic blood pressure (SBP) - All Treated Population[13][14]

End point description:

DBP and SBP were measured after resting for at least 5 minutes in a supine or semi-recumbent position. They were graded according to NCI-CTCAE version 4.03. For SBP: Grade 0 (<=120 millimeter of mercury [mmHg]), Grade 1 (121-139 mmHg), Grade 2 (140-159 mmHg), Grade 3 (>=160 mmHg). For DBP: Grade 0 (<=80 mmHg), Grade 1 (81-89 mmHg), Grade 2 (90-99 mmHg), Grade 3 (>=100

mmHg). Higher grade indicates greater severity. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Data for worst-case post baseline with any grade increase and a maximum post-baseline grade increase to Grade 3 from their baseline grade are presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 31 months

Notes:

[13] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
DBP, Any Grade Increase	6	4		
DBP, Increase to Grade 2	2	1		
DBP, Increase to Grade 3	0	0		
SBP, Any Grade Increase	6	5		
SBP, Increase to Grade 2	3	2		
SBP, Increase to Grade 3	0	3		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with worst-case change from baseline in vital signs: pulse rate and body temperature - All Treated Population

End point title	Part 1 - Number of participants with worst-case change from baseline in vital signs: pulse rate and body temperature - All Treated Population[15][16]

End point description:

Vital signs (pulse rate and temperature) were measured after resting for at least 5 minutes in a supine or semi-recumbent position. The abnormal vital sign ranges were: For pulse rate (low <60 beats per minute [bpm] and high >100 bpm); For body temperature (<=35 degrees Celsius or >=38 degrees Celsius). Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Data for worst case change from baseline was presented as Baseline to low, Baseline to Normal or No change and Baseline to High.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 31 months

Notes:

[15] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
Pulse Rate|Baseline To Low	3	2		
Temperature|Baseline To Low	0	1		
Pulse Rate|Baseline To Normal or No Change	3	3		
Temperature|Baseline To Normal or No Change	4	6		
Pulse Rate|Baseline To High	0	2		
Temperature|Baseline To High	2	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part 2 - Percentage of participants with overall response rate (ORR) - All Treated Population

End point title	Part 2 - Percentage of participants with overall response rate (ORR) - All Treated Population[17][18]

End point description:

ORR was defined as the percentage of participants with a confirmed partial response (PR) or better (i.e., PR, very good partial response [VGPR], complete response [CR] and stringent complete response [sCR]), according to the International Myeloma Working Group (IMWG) Response Criteria. CR = negative immunofixation of serum and urine AND disappearance of any soft tissue plasmacytomas AND <5% plasmacytomas in the bone marrow; sCR=stringent complete response, CR as above PLUS normal serum free light-chain (FLC) assay ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence; VGPR = serum and urine M-component detectable by immunofixation but not on electrophoresis OR ≥ 90% reduction in serum M-component plus urine M-component <100 mg/24 h; PR = ≥50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥90% or to <200 mg/24 h.

End point type	Primary

End point timeframe:

Up to approximately 31 months

Notes:

[17] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Percentage of Participants				
number (confidence interval 95%)	43 (24.5 to 62.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Number of participants with worst-case change post-baseline urinalysis results - All Treated Population

End point title	Part 1 - Number of participants with worst-case change post-baseline urinalysis results - All Treated Population[19][20]

End point description:

Urine samples were collected to assess urine glucose, protein, occult blood and ketones using dipstick method. The dipstick test gave results in a semi-quantitative manner, and results for urinalysis parameters were recorded as negative, trace, 1+, 2+, 3+ indicating proportional concentrations in the urine sample. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Result for urinalysis parameters were recorded as no change/decreased and any increase. Data for worst-case post baseline urinalysis results is presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 31 months

Notes:

[19] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Participants				
Glucose, No Change/Decreased	6	5		

Glucose, Any Increase	0	1		
Ketones, No Change/Decreased	3	5		
Ketones, Any Increase	3	1		
Occult Blood, No Change/Decreased	4	4		
Occult Blood, Any Increase	2	1		
Protein, No Change/Decreased	4	4		
Protein, Any Increase	2	2		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Changes from baseline in urine potential of hydrogen (pH) - All Treated Population

End point title	Part 1 - Changes from baseline in urine potential of hydrogen (pH) - All Treated Population[21][22]

End point description:

Urine samples were collected from participants to assess urine pH levels. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. 99999= Mean and standard deviation is not applicable as only a single participant was analyzed.

End point type	Primary

End point timeframe:

Baseline (Day 1) and Week 46

Notes:

[21] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Potential of Hydrogen (pH)				
arithmetic mean (standard deviation)	1.0 (± 2.83)	0.0 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Primary: Part 1 - Changes from baseline in urine specific gravity - All Treated Population

End point title	Part 1 - Changes from baseline in urine specific gravity - All Treated Population[23][24]

End point description:

Urine samples were collected from participants to assess urine specific gravity. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. 99999= Mean and standard deviation is not applicable as only a single participant was analyzed.

End point type	Primary

End point timeframe:

Baseline (Day 1) and Week 46

Notes:

[23] - 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: The primary endpoint of the study was planned to analyses with only descriptive statistics. Hence, no statistical analysis was performed.
[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: Ratio				
arithmetic mean (standard deviation)	-0.0010 (± 0.00566)	0.0100 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Percentage of Participants With Overall Response Rate (ORR) - All Treated Population

End point title	Part 1 - Percentage of Participants With Overall Response Rate (ORR) - All Treated Population[25]

End point description:

ORR was defined as the percentage of participants with a confirmed PR or better (i.e., PR, VGPR, CR and sCR), according to the IMWG Response Criteria. CR = negative immunofixation of serum and urine AND disappearance of any soft tissue plasmacytomas AND <5% plasmacytomas in the bone marrow; sCR=stringent complete response, CR as above PLUS normal serum free light-chain (FLC) assay ratio and absence of clonal cells in bone marrow by immunohistochemistry or immunofluorescence; VGPR = serum and urine M-component detectable by immunofixation but not on electrophoresis OR >= 90% reduction in serum M-component plus urine M-component <100 mg/24 h; PR = >=50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by >=90% or to <200 mg/24 h.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint,

results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: Percentage of Participants				
number (confidence interval 95%)	67 (22.3 to 95.7)	43 (9.9 to 81.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With AEs and SAEs - All Treated Population

End point title	Part 2 - Number of Participants With AEs and SAEs - All Treated Population[26]

End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations which involve medical or scientific judgment or is associated with liver injury and impaired liver function.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Participants				
AEs	27			
SAEs	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Grade Change From Baseline in Hematology Parameters - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Grade Change From Baseline in Hematology Parameters - All Treated Population[27]

End point description:

Blood samples were collected for the analysis of following hematology parameters: hemoglobin, White blood cell (WBC) count, lymphocytes, neutrophils and platelet. The laboratory parameters were graded according to NCI-CTCAE version 4.03. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life-threatening consequences. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Any worst case post baseline increase in grade along with any increase to a maximum grade of 3 and a maximum grade of 4 are presented.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:Belantamab Mafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Participants				
Anemia, Any Grade Increase	10			
Anemia, Increase to Grade 3	3			
Anemia, Increase to Grade 4	0			
Hemoglobin increased, Any Grade Increase	2			
Hemoglobin increased, Increase to Grade 3	0			
Hemoglobin increased, Increase to Grade 4	0			
Leukocytosis, Any Grade Increase	1			
Leukocytosis, Increase to Grade 3	0			
Leukocytosis, Increase to Grade 4	0			
WBC decreased, Any Grade Increase	11			
WBC decreased, Increase to Grade 3	1			
WBC decreased, Increase to Grade 4	2			
Lymphocyte count decreased, Any Grade Increase	14			
Lymphocyte count decreased, Increase to Grade 3	3			
Lymphocyte count decreased, Increase to Grade 4	4			

Lymphocyte count increased, Any Grade Increase	2			
Lymphocyte count increased, Increase to Grade 3	1			
Lymphocyte count increased, Increase to Grade 4	0			
Neutrophil count decreased, Any Grade Increase	9			
Neutrophil count decreased, Increase to Grade 3	1			
Neutrophil count decreased, Increase to Grade 4	2			
Platelet count decreased, Any Grade Increase	18			
Platelet count decreased, Increase to Grade 3	7			
Platelet count decreased, Increase to Grade 4	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Change Post-baseline in Hematology Parameters - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Change Post-baseline in Hematology Parameters - All Treated Population[28]

End point description:

Blood samples were collected for the analysis of following hematology parameters: basophils, eosinophils, mean corpuscular hemoglobin concentration (MCHC), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), Erythrocytes, hematocrit, monocytes, neutrophils and reticulocyte. The summaries of worst-case change from baseline with respect to normal range was analyzed for only those laboratory tests that were not gradable by CTCAE version 4.03. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. The number of participants with decreases to low from baseline, changes to normal or no changes from baseline, and increases to high values have been presented.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Participants				
Basophils, Decrease to Low	0			

Basophils, Change to Normal or No Change	22			
Basophils, Increase to High	1			
Eosinophils, Decrease to Low	2			
Eosinophils, Change to Normal or No Change	22			
Eosinophils, Increase to High	3			
MCHC, Decrease to Low	3			
MCHC, Change to Normal or No Change	24			
MCHC, Increase to High	0			
MCH, Decrease to Low	3			
MCH, Change to Normal or No Change	16			
MCH, Increase to High	3			
MCV, Decrease to Low	0			
MCV, Change to Normal or No Change	25			
MCV, Increase to High	2			
Erythrocytes, Decrease to Low	0			
Erythrocytes, Change to Normal or No Change	26			
Erythrocytes, Increase to High	1			
Hematocrit, Decrease to Low	3			
Hematocrit, Change to Normal or No Change	23			
Hematocrit, Increase to High	1			
Monocytes, Decrease to Low	0			
Monocytes, Change to Normal or No Change	20			
Monocytes, Increase to High	7			
Neutrophils, Segmented, Decrease to Low	0			
Neutrophils,Segmented,Change to Normal/No Change	1			
Neutrophils, Segmented, Increase to High	0			
Reticulocytes, Decrease to Low	2			
Reticulocytes, Change to Normal/No Change	14			
Reticulocytes, Increase to High	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Grade Change From Baseline in Lab Chemistry Parameters - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Grade Change From Baseline in Lab Chemistry Parameters - All Treated Population[29]

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters: glucose, alanine aminotransferase (ALT), albumin, alkaline phosphatase, aspartate aminotransferase (AST), blood bilirubin, calcium, creatine kinase (CPK), creatinine, gamma glutamyl transferase (GGT), magnesium, phosphate potassium and sodium. Laboratory parameters were graded according to NCI-CTCAE version 4.03. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life-

threatening consequences. Higher grade indicates greater severity and an increase in CTCAE grade was defined relative to the Baseline grade. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Any worst case post baseline increase in grade along with any increase to a maximum grade of 3 and a maximum grade of 4 are presented.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Participants				
Hyperglycemia, Any Grade Increase	1			
Hyperglycemia, Increase to Grade 3	0			
Hyperglycemia, Increase to Grade 4	0			
Hypoglycemia, Any Grade Increase	4			
Hypoglycemia, Increase to Grade 3	0			
Hypoglycemia, Increase to Grade 4	0			
ALT increased, Any Grade Increase	5			
ALT increased, Increase to Grade 3	1			
ALT increased, Increase to Grade 4	0			
Hypoalbuminemia, Any Grade Increase	9			
Hypoalbuminemia, Increase to Grade 3	1			
Hypoalbuminemia, Increase to Grade 4	0			
Alkalinephosphatase increased, Any Grade Increase	9			
Alkalinephosphatase increased, Increase to Grade 3	1			
Alkalinephosphatase increased, Increase to Grade 4	0			
AST increased, Any Grade Increase	20			
AST increased, Increase to Grade 3	1			
AST increased, Increase to Grade 4	0			
Blood bilirubin increased, Any Grade Increase	3			
Blood bilirubin increased, Increase to Grade 3	1			
Blood bilirubin increased, Increase to Grade 4	0			
Hypercalcemia, Any Grade Increase	3			
Hypercalcemia, Increase to Grade 3	0			
Hypercalcemia, Increase to Grade 4	0			
Hypocalcemia, Any Grade Increase	3			
Hypocalcemia, Increase to Grade 3	0			
Hypocalcemia, Increase to Grade 4	0			
CPK increased, Any Grade Increase	4			

CPK increased, Increase to Grade 3	1			
CPK increased, Increase to Grade 4	0			
Creatinine increased, Any Grade Increase	7			
Creatinine increased, Increase to Grade 3	0			
Creatinine increased, Increase to Grade 4	0			
GGT increased, Any Grade Increase	10			
GGT increased, Increase to Grade 3	1			
GGT increased, Increase to Grade 4	0			
Hypermagnesemia, Any Grade Increase	0			
Hypermagnesemia, Increase to Grade 3	0			
Hypermagnesemia, Increase to Grade 4	0			
Hypomagnesemia, Any Grade Increase	6			
Hypomagnesemia, Increase to Grade 3	0			
Hypomagnesemia, Increase to Grade 4	0			
Hypophosphatemia, Any Grade Increase	3			
Hypophosphatemia, Increase to Grade 3	1			
Hypophosphatemia, Increase to Grade 4	0			
Hyperkalemia, Any Grade Increase	0			
Hyperkalemia, Increase to Grade 3	0			
Hyperkalemia, Increase to Grade 4	0			
Hypokalemia, Any Grade Increase	4			
Hypokalemia, Increase to Grade 3	1			
Hypokalemia, Increase to Grade 4	0			
Hypernatremia, Any Grade Increase	0			
Hypernatremia, Increase to Grade 3	0			
Hypernatremia, Increase to Grade 4	0			
Hyponatremia, Any Grade Increase	3			
Hyponatremia, Increase to Grade 3	1			
Hyponatremia, Increase to Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Change Post-baseline in Lab Chemistry Parameters - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Change Post-baseline in Lab Chemistry Parameters - All Treated Population[30]

End point description:

Blood samples were collected for the analysis of following chemistry parameters: calcium, carbon dioxide, chloride, direct bilirubin, protein, thyrotropin (TSH), thyroxine (T4) and triiodothyronine (T3). Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. The summaries of worst case change from baseline with respect to normal range was analyzed for only those laboratory tests that were not gradable by CTCAE version 4.03. The number of participants with decreases to low, changes to normal or no changes from baseline, and increases to high values have been presented.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:Belantamab Mafodotin 2.5 mg/kg+Pembrolizumab 200mg			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Participants				
Calcium, Decrease to Low	4			
Calcium, Change to Normal or No Change	18			
Calcium, Increase to High	5			
Carbon Dioxide, Decrease to Low	4			
Carbon Dioxide, Change to Normal or No Change	14			
Carbon Dioxide, Increase to High	9			
Chloride, Decrease to Low	4			
Chloride, Change to Normal or No Change	20			
Chloride, Increase to High	3			
Direct Bilirubin, Decrease to Low	2			
Direct Bilirubin, Change to Normal or No Change	15			
Direct Bilirubin, Increase to High	7			
Protein, Decrease to Low	8			
Protein, Change to Normal or No Change	18			
Protein, Increase to High	2			
TSH, Decrease to Low	1			
TSH, Change to Normal or No Change	17			
TSH, Increase to High	8			
T4, Free, Decrease to Low	2			
T4, Free, Change to Normal or No Change	23			
T4, Free, Increase to High	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Changes From Baseline in Urine Specific Gravity - All Treated Population

End point title	Part 2 - Changes From Baseline in Urine Specific Gravity - All Treated Population[31]

End point description:

Urine samples were collected from participants to assess urine specific gravity. Baseline was defined as

the most recent, non-missing value prior to or on the first study treatment dose date

End point type	Secondary

End point timeframe:

Baseline (Day 1) and until end of treatment (up to 178 weeks)

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:Belantamab Mafodotin 2.5 mg/kg+Pembrolizumab 200mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Ratio				
arithmetic mean (standard deviation)				
Baseline	1.0171 (± 0.00965)			
End of Treatment	-0.0001 (± 0.00813)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Change Post-baseline Urinalysis Results - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Change Post-baseline Urinalysis Results - All Treated Population[32]

End point description:

Urine samples were collected to assess urine glucose, protein, occult blood and ketones using dipstick method. The dipstick test gave results in a semi-quantitative manner, and results for urinalysis parameters were recorded as negative, trace, 1+, 2+, 3+ indicating proportional concentrations in the urine sample. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Result for uranalysis parameters were recorded as no change/decreased and any increase. Data for worst-case post baseline are presented.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Participants				
Glucose, No Change/Decreased	25			
Glucose, Any Increase	1			
Ketones, No Change/Decreased	21			
Ketones, Any Increase	5			
Occult Blood, No Change/Decreased	15			
Occult Blood, Any Increase	9			
Protein, No Change/Decreased	20			
Protein, Any Increase	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Changes From Baseline in Urine pH - All Treated Population

End point title	Part 2 - Changes From Baseline in Urine pH - All Treated Population[33]

End point description:

Urine samples were collected from participants to assess urine pH levels. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and until end of treatment (up to 178 weeks)

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Potential of Hydrogen (pH)				
arithmetic mean (standard deviation)				
Baseline	5.71 (± 0.844)			
End of Treatment	0.10 (± 0.687)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Grade Change From Baseline in Vital Signs: DBP and SBP - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Grade Change From Baseline in Vital Signs: DBP and SBP - All Treated Population[34]

End point description:

DBP and SBP were measured after resting for at least 5 minutes in a supine or semi-recumbent position. They were graded according to NCI-CTCAE version 4.0. For SBP: Grade 0 (<=120 millimeter of mercury [mmHg]), Grade 1 (121-139 mmHg), Grade 2 (140-159 mmHg), Grade 3 (>=160 mmHg). For DBP: Grade 0 (<=80 mmHg), Grade 1 (81-89 mmHg), Grade 2 (90-99 mmHg), Grade 3 (>=100 mmHg). Higher grade indicates greater severity. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. An increase is defined as an increase in grade relative to Baseline grade. Data for worst-case post Baseline with any grade increase and a maximum post-baseline grade increase to Grade 3 from their baseline grade are presented.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Participants				
DBP, Any Grade Increase	20			
DBP, Increase to Grade 2	12			
DBP, Increase to Grade 3	2			
SBP, Any Grade Increase	24			
SBP, Increase to Grade 2	16			
SBP, Increase to Grade 3	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Change From Baseline in Vital Signs: Pulse Rate and Body Temperature - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Change From Baseline in Vital Signs: Pulse Rate and Body Temperature - All Treated Population[35]

End point description:

Vital signs (pulse rate and temperature) were measured after resting for at least 5 minutes in a supine or semi-recumbent position. The abnormal vital sign ranges were: For pulse rate (low <60 beats per

minute [bpm] and high >100 bpm); For body temperature (<=35 degrees Celsius or >=38 degrees Celsius). Participants were counted in the worst case category that their value changed to (low, normal or high), unless there was no change in their category. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Participants				
Pulse Rate, To Low	10			
Pulse Rate, To Normal or No Change	11			
Pulse Rate, To High	7			
Temperature, To Low	2			
Temperature, To Normal or No Change	23			
Temperature, To High	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Maximum Worst-case Change From Baseline in Best Corrected Visual Acuity Test (BCVA) Scores - All Treated Population

End point title	Part 2 - Number of Participants With Maximum Worst-case Change From Baseline in Best Corrected Visual Acuity Test (BCVA) Scores - All Treated Population[36]

End point description:

BCVA score was calculated based on the Logarithm of the Minimum Angle of Resolution (logMAR score). Any maximum worst-case change from baseline categories are presented for right and left eyes. No change/improved vision is defined as a change from baseline <0.12; a possible worsened vision is defined as a change from baseline >=0.12 to <0.3; a definite worsened vision is defined as a change from baseline >=0.3 logMAR score. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Participants				
Left Eye, No change/improved vision	14			
Left Eye, Possible worsened vision	5			
Left Eye, Definite worsened vision	8			
Right Eye, No change/improved vision	16			
Right Eye, Possible worsened vision	4			
Right Eye, Definite worsened vision	7			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Duration of First Occurrence of Worsening in BCVA Score - All Treated Population

End point title	Part 2 - Duration of First Occurrence of Worsening in BCVA Score - All Treated Population[37]

End point description:

The time from onset of any visual acuity event (change from baseline logMAR score >= 0.3 in either eye) until the event is resolved (change from baseline logMAR score < 0.3 in both eyes) was used to calculate the duration of first occurrence.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Days				
median (full range (min-max))	47.0 (3 to 65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Outcome of First Occurrence of Worsening Eye in BCVA Score - All Treated Population

End point title	Part 2 - Outcome of First Occurrence of Worsening Eye in BCVA Score - All Treated Population[38]

End point description:

The onset of any visual acuity event (change from baseline in logMAR score >= 0.3 in either eye) was considered resolved if the change from baseline in logMAR score was less than 0.3 in both eyes. Participants with resolved and not resolved outcome of the worsening eye were presented.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Participants				
Resolved prior to end of treatment exposure	7			
Resolved post end of treatment exposure	2			
Not resolved	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Time Taken for the Onset of First Occurrence of Worsening in BCVA Score - All Treated Population

End point title	Part 2 - Time Taken for the Onset of First Occurrence of Worsening in BCVA Score - All Treated Population[39]

End point description:

The time for the onset of any visual acuity event (change from baseline logMAR score >= 0.3 in either eye) was calculated.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Days				
median (full range (min-max))	78.0 (37 to 273)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants According to the Number of Definite Events of Worsening of Vision - All Treated Population

End point title	Part 2 - Number of Participants According to the Number of Definite Events of Worsening of Vision - All Treated Population[40]

End point description:

A definite worsened vision was defined as a change from baseline >=0.3 logMAR score.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Participants				
One	6			
Two	1			
Three or more	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Resolution of Post Treatment Exposure Worsening in BCVA Score - All Treated Population

End point title	Part 2 - Number of Participants With Resolution of Post Treatment Exposure Worsening in BCVA Score - All Treated Population[41]

End point description:

The event was considered resolved if the change from baseline in logMAR score < 0.3 in both eyes.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Participants				
Resolved	2			
Not resolved, follow-up ongoing	0			
Not resolved, follow-up ended	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Shift From Baseline in Ophthalmological Epithelium Exam - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Shift From Baseline in Ophthalmological Epithelium Exam - All Treated Population[42]

End point description:

Participants with worst-case shift from baseline in corneal epithelium defects by right eye, left eye and worse eye are presented as normal (N), abnormal (AN) and missing. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Participants				
Left, Normal, Abnormal	16			
Left, Normal, Missing	1			
Left, Abnormal, Normal	1			
Left, Abnormal, Abnormal	8			
Left, Abnormal, Missing	0			
Right, Normal, Abnormal	16			
Right, Normal, Missing	0			
Right, Abnormal, Normal	0			
Right, Abnormal, Abnormal	8			
Right, Abnormal, Missing	1			
Worse Eye, Normal, Abnormal	17			
Worse Eye, Normal, Missing	1			
Worse Eye, Abnormal, Normal	0			
Worse Eye, Abnormal, Abnormal	7			
Worse Eye, Abnormal, Missing	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Duration of Resolution Post-treatment Exposure of Worsening in BCVA Score - All Treated Population

End point title	Part 2 - Duration of Resolution Post-treatment Exposure of Worsening in BCVA Score - All Treated Population[43]

End point description:

The time taken for the resolution of worsening eye post treatment exposure. Duration was defined as the time from onset of any visual acuity event (change from baseline logMAR score >= 0.3 in either eye) until the event was considered resolved (change from baseline logMAR score < 0.3 in both eyes). It required at least a one day gap between the resolution of all events from first occurrence to the onset of second occurrence. The end of treatment exposure was defined as 20 days from last infusion date.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Days				
median (full range (min-max))	34.5 (22 to 47)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Post-baseline Decline in BCVA to Light Perception or no Light Perception - All Treated Population

End point title	Part 2 - Number of Participants With Post-baseline Decline in BCVA to Light Perception or no Light Perception - All Treated Population[44]

End point description:

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[45]			
Units: Participants				
number (not applicable)				

Notes:

[45] - Data was not collected

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Shift From Baseline in Corneal Examinations - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Shift From Baseline in Corneal Examinations - All Treated Population[46]

End point description:

Participants with worst-case shift from baseline in corneal examination: corneal ulcer, epithelial microcystic edema, subepithelial haze, corneal neovascularization and microcysts without edema, by right eye (R), left eye (L) and worse eye (W) are presented as yes (Y), no (N) and missing (M). Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Participants				
Corneal Ulcer Indicator, Left (L), No (N), No	23			
Corneal Ulcer Indicator, Left, No, Yes (Y 0	0			
Corneal Ulcer Indicator, Left, No, Missing	1			
Corneal Ulcer Indicator, Left, Yes, No	0			
Corneal Ulcer Indicator, Left, Yes, Yes	0			
Corneal Ulcer Indicator, Left, Yes, Missing	0			
Corneal Ulcer Indicator, Left, Missing (M), No	3			
Corneal Ulcer Indicator, Left, Missing, Yes	0			
Corneal Ulcer Indicator, Left, Missing, Missing	1			
Corneal Ulcer Indicator, Right (R), No, No	21			
Corneal Ulcer Indicator, Right, No, Yes	0			
Corneal Ulcer Indicator, Right, No, Missing	1			
Corneal Ulcer Indicator, Right, Yes, No	0			
Corneal Ulcer Indicator, Right, Yes, Yes	0			
Corneal Ulcer Indicator, Right, Yes, Missing	0			
Corneal Ulcer Indicator, Right, Missing, No	5			
Corneal Ulcer Indicator, Right, Missing, Yes	0			
Corneal Ulcer Indicator, Right, Missing, Missing	1			
Corneal Ulcer Indicator, Worse Eye (WE), No, No	23			
Corneal Ulcer Indicator, Worse Eye, No, Yes	0			

Corneal Ulcer Indicator, Worse Eye, No, Missing	1			
Corneal Ulcer Indicator, Worse Eye, Yes, No	0			
Corneal Ulcer Indicator, Worse Eye, Yes, Yes	0			
Corneal Ulcer Indicator, Worse Eye, Yes, Missing	0			
Corneal Ulcer Indicator, Worse Eye, Missing, No	3			
Corneal Ulcer Indicator, Worse Eye, M, Y	0			
Corneal Ulcer Indicator, Worse Eye, M, M	1			
Epithelial Microcystic Edema Indicator, L, N, N	17			
Epithelial Microcystic Edema Indicator, L, N, Y	6			
Epithelial Microcystic Edema Indicator, L,N, M	1			
Epithelial Microcystic Edema Indicator, L, Y, N	0			
Epithelial Microcystic Edema Indicator, L, Y, Y	0			
Epithelial Microcystic Edema Indicator, L, Y, M	0			
Epithelial Microcystic Edema Indicator, L, M, N	2			
Epithelial Microcystic Edema Indicator, L, M, Y	1			
Epithelial Microcystic Edema Indicator, L, M, M	1			
Epithelial Microcystic Edema Indicator, R, N, N	16			
Epithelial Microcystic Edema Indicator, R, N, Y	5			
Epithelial Microcystic Edema Indicator, R, N, M	1			
Epithelial Microcystic Edema Indicator, Rt, Y, N	0			
Epithelial Microcystic Edema Indicator, R, Y, Y	0			
Epithelial Microcystic Edema Indicator, R, Y, M	0			
Epithelial Microcystic Edema Indicator, R, M, N	3			
Epithelial Microcystic Edema Indicator, R, M, Y	2			
Epithelial Microcystic Edema Indicator, R, M, M	1			
Epithelial Microcystic Edema Indicator, WE, N, N	17			
Epithelial Microcystic Edema Indicator,WE, N, Y	6			
Epithelial Microcystic Edema Indicator, WE, N, M	1			
Epithelial Microcystic Edema Indicator, WE, Y, N	0			
Epithelial Microcystic Edema Indicator, WE, Y, Y	0			
Epithelial Microcystic Edema Indicator, WE, Y, M	0			

Epithelial Microcystic Edema Indicator, WE, M, N	2			
Epithelial Microcystic Edema Indicator, WE, M, Y	1			
Epithelial Microcystic Edema Indicator, WE, M, M	1			
Microcysts Without Edema Indicator, L, N, N	8			
Microcysts Without Edema Indicator, L, N, Y	15			
Microcysts Without Edema Indicator, L, N, M	1			
Microcysts Without Edema Indicator, L, Y, N	0			
Microcysts Without Edema Indicator, L, Y, Y	0			
Microcysts Without Edema Indicator, L, Y, M	0			
Microcysts Without Edema Indicator, L, M, N	0			
Microcysts Without Edema Indicator, L, M, Y	3			
Microcysts Without Edema Indicator, L, M, M	1			
Microcysts Without Edema Indicator, R, N, N	7			
Microcysts Without Edema Indicator, R, N, Y	14			
Microcysts Without Edema Indicator, R, N, M	1			
Microcysts Without Edema Indicator, R, Y, N	0			
Microcysts Without Edema Indicator, R, Y, Y	0			
Microcysts Without Edema Indicator, R, Y, M	0			
Microcysts Without Edema Indicator, R, M, N	1			
Microcysts Without Edema Indicator, R, M, Y	4			
Microcysts Without Edema Indicator, R, M, M	1			
Microcysts Without Edema Indicator, WE, N, N	8			
Microcysts Without Edema Indicator, WE, N, Y	15			
Microcysts Without Edema Indicator, WE, N, M	1			
Microcysts Without Edema Indicator, WE, Y, N	0			
Microcysts Without Edema Indicator, WE, Y, Y	0			
Microcysts Without Edema Indicator, WE, Y, M	0			
Microcysts Without Edema Indicator, WE, M, N	0			
Microcysts Without Edema Indicator, WE, M, Y	3			
Microcysts Without Edema Indicator, WE, M, M	1			
Neovascularization Indicator, Left, No, No	22			

Neovascularization Indicator, Left, No, Yes	1			
Neovascularization Indicator, Left, No, Missing	2			
Neovascularization Indicator, Left, Yes, No	0			
Neovascularization Indicator, Left, Yes, Yes	0			
Neovascularization Indicator, Left, Yes, Missing	0			
Neovascularization Indicator, Left, Missing, No	2			
Neovascularization Indicator, Left, Missing, Yes	1			
Neovascularization Indicator, L, M, M	0			
Neovascularization Indicator, R, N, N	20			
Neovascularization Indicator, R, N, Y	1			
Neovascularization Indicator, R, N, M	2			
Neovascularization Indicator, R, Y, N	0			
Neovascularization Indicator, R, Y, Y	1			
Neovascularization Indicator, R, Y, M	0			
Neovascularization Indicator, R, M, N	3			
Neovascularization Indicator, R, M, Y	1			
Neovascularization Indicator, R, M, M	0			
Neovascularization Indicator, WE, N, N	21			
Neovascularization Indicator, WE, N, Y	1			
Neovascularization Indicator, WE, N, M	2			
Neovascularization Indicator, WE, Y, N	0			
Neovascularization Indicator, WE, Y, Y	1			
Neovascularization Indicator, WE, Y, M	0			
Neovascularization Indicator, WE, M, N	2			
Neovascularization Indicator, WE, M, Y	1			
Neovascularization Indicator, WE, M, M	0			
Subepithelial Haze Indicator, L, N, N	16			
Subepithelial Haze Indicator, L, N, Y	9			
Subepithelial Haze Indicator, L, N, M	1			
Subepithelial Haze Indicator, Left, Yes, No	1			
Subepithelial Haze Indicator, Left, Yes, Yes	0			
Subepithelial Haze Indicator, Left, Yes, M	0			
Subepithelial Haze Indicator, Left, M, No	1			
Subepithelial Haze Indicator, L, M, Yes	0			
Subepithelial Haze Indicator, L, M, M	0			
Subepithelial Haze Indicator, R, No, No	16			
Subepithelial Haze Indicator, R, No, Yes	8			
Subepithelial Haze Indicator, R, No, M	1			
Subepithelial Haze Indicator, R, Yes, No	1			
Subepithelial Haze Indicator, R, Yes, Yes	0			
Subepithelial Haze Indicator, R, Yes, M	0			
Subepithelial Haze Indicator, R, M, No	2			
Subepithelial Haze Indicator, R, M, Yes	0			
Subepithelial Haze Indicator, R, M, M	0			

Subepithelial Haze Indicator, WE, No, No	17			
Subepithelial Haze Indicator, WE, No, Yes	9			
Subepithelial Haze Indicator, Worse Eye, No, M	1			
Subepithelial Haze Indicator, WE, Yes, No	0			
Subepithelial Haze Indicator, WE, Yes, Y	0			
Subepithelial Haze Indicator, WE, Y, M	0			
Subepithelial Haze Indicator, WE, M, No	1			
Subepithelial Haze Indicator, Worse Eye, M, Yes	0			
Subepithelial Haze Indicator, Worse Eye, M, M	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worse Case Post-baseline Punctate Keratopathy Findings - All Treated Population

End point title	Part 2 - Number of Participants With Worse Case Post-baseline Punctate Keratopathy Findings - All Treated Population[47]

End point description:

Participants with worse case punctate keratopathy findings post baseline at any ocular exam by right eye, left eye and worse eye are presented as none, mild, moderate and severe. Worse eye indicates the eye with the worst visual acuity. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Worst finding among post-baseline exams = WPBE; Most frequent finding among post-baseline exams = MPBE.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:Belantamab Mafodotin 2.5 mg/kg+Pembrolizumab 200mg			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Participants				
Left, WPBE, NONE	2			
Left, WPBE, MILD	9			
Left, WPBE, MODERATE	9			
Left, WPBE, SEVERE	6			
Left, MPBE, NONE	8			
Left, MPBE, MILD	13			

Left, MPBE, MODERATE	5			
Left, MPBE, SEVERE	0			
Right, WPBE, NONE	2			
Right, WPBE, MILD	11			
Right, WPBE, MODERATE	7			
Right, WPBE, SEVERE	6			
Right, MPBE, NONE	10			
Right, MPBE, MILD	14			
Right, MPBE, MODERATE	2			
Right, MPBE, SEVERE	0			
Worse Eye, WPBE, NONE	2			
Worse Eye, WPBE, MILD	8			
Worse Eye, WPBE, MODERATE	10			
Worse Eye, WPBE, SEVERE	6			
Worse Eye, MPBE, NONE	7			
Worse Eye, MPBE, MILD	14			
Worse Eye, MPBE, MODERATE	5			
Worse Eye, MPBE, SEVERE	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Worst-case Shift From Baseline in Lens Examinations - All Treated Population

End point title	Part 2 - Number of Participants With Worst-case Shift From Baseline in Lens Examinations - All Treated Population[48]

End point description:

Participants with worst-case shift from baseline in corneal examination which included: clear, pseudophakia, nuclear sclerosis, cortical cataract and posterior subcapsular cataract by right eye, left eye and worse eye are presented as yes (Y), no (N) and missing. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Participants				
Clear Indicator, Left, No, No	12			
Clear Indicator, Left, No, Yes	0			

Clear Indicator, Left, No, Missing	3			
Clear Indicator, Left, Yes, No	3			
Clear Indicator, Left, Yes, Yes	10			
Clear Indicator, Left, Yes, Missing	0			
Clear Indicator, Left, Missing, No	0			
Clear Indicator, Left, Missing, Yes	0			
Clear Indicator, Left, Missing, Missing	0			
Clear Indicator, Right, No, No	12			
Clear Indicator, Right, No, Yes	0			
Clear Indicator, Right, No, Missing	3			
Clear Indicator, Right, Yes, No	3			
Clear Indicator, Right, Yes, Yes	10			
Clear Indicator, Right, Yes, Missing	0			
Clear Indicator, Right, Missing, No	0			
Clear Indicator, Right, Missing, Yes	0			
Clear Indicator, Right, Missing, Missing	0			
Clear Indicator, Worse Eye, No, No	12			
Clear Indicator, Worse Eye, No, Yes	0			
Clear Indicator, Worse Eye, No, Missing	3			
Clear Indicator, Worse Eye, Yes, No	3			
Clear Indicator, Worse Eye, Yes, Yes	10			
Clear Indicator, Worse Eye, Yes, Missing	0			
Clear Indicator, Worse Eye, Missing, No	0			
Clear Indicator, Worse Eye, Missing, Yes	0			
Clear Indicator, Worse Eye, Missing, Missing	0			
Cortical Cataract Indicator, Left, No, No	7			
Cortical Cataract Indicator, Left, No, Yes	3			
Cortical Cataract Indicator, Left, No, Missing	2			
Cortical Cataract Indicator, Left, Yes, No	0			
Cortical Cataract Indicator, Left, Yes, Yes	2			
Cortical Cataract Indicator, Left, Yes, Missing	1			
Cortical Cataract Indicator, Left, Missing, No	2			
Cortical Cataract Indicator, Left, M, Yes	1			
Cortical Cataract Indicator, Left, M, M	10			
Cortical Cataract Indicator, Right, No, No	7			
Cortical Cataract Indicator, Right, N, Y	3			
Cortical Cataract Indicator, Right, No, M	1			
Cortical Cataract Indicator, Right, Yes, No	0			
Cortical Cataract Indicator, Right, Yes, Yes	2			
Cortical Cataract Indicator, Right, Yes, M	2			
Cortical Cataract Indicator, Right, M, No	3			
Cortical Cataract Indicator, Right, M, Yes	0			
Cortical Cataract Indicator, Right, M, M	10			
Cortical Cataract Indicator, Worse Eye, No, No	7			

Cortical Cataract Indicator, Worse Eye, No, Yes	3			
Cortical Cataract Indicator, Worse Eye, No, M	2			
Cortical Cataract Indicator, Worse Eye, Yes, No	0			
Cortical Cataract Indicator, Worse Eye, Yes, Yes	2			
Cortical Cataract Indicator, WE, Yes, M	1			
Cortical Cataract Indicator, WE, Missing, No	2			
Cortical Cataract Indicator, WE, Missing, Yes	1			
Cortical Cataract Indicator, WE, M, M	10			
Nuclear Sclerosis Indicator, Left, No, No	2			
Nuclear Sclerosis Indicator, Left, No, Yes	1			
Nuclear Sclerosis Indicator, Left, No, M	0			
Nuclear Sclerosis Indicator, Left, Yes, No	1			
Nuclear Sclerosis Indicator, Left, Yes, Yes	8			
Nuclear Sclerosis Indicator, Left, Yes, M	3			
Nuclear Sclerosis Indicator, Left, M, No	2			
Nuclear Sclerosis Indicator, Left, M, Yes	1			
Nuclear Sclerosis Indicator, Left, M, M	10			
Nuclear Sclerosis Indicator, Right, No, No	2			
Nuclear Sclerosis Indicator, Right, No, Yes	1			
Nuclear Sclerosis Indicator, Right, No, M	0			
Nuclear Sclerosis Indicator, Right, Yes, No	1			
Nuclear Sclerosis Indicator, Right, Yes, Yes	8			
Nuclear Sclerosis Indicator, Right, Yes, M	3			
Nuclear Sclerosis Indicator, Right, M, No	3			
Nuclear Sclerosis Indicator, Right, M, Yes	0			
Nuclear Sclerosis Indicator, Right, M, M	10			
Nuclear Sclerosis Indicator, Worse Eye, No, No	2			
Nuclear Sclerosis Indicator, Worse Eye, No, Yes	1			
Nuclear Sclerosis Indicator, Worse Eye, No, M	0			
Nuclear Sclerosis Indicator, Worse Eye, Yes, No	1			
Nuclear Sclerosis Indicator, Worse Eye, Yes, Yes	8			
Nuclear Sclerosis Indicator, Worse Eye, Yes, M	3			
Nuclear Sclerosis Indicator, Worse Eye, M, No	2			
Nuclear Sclerosis Indicator, Worse Eye, M, Yes	1			
Nuclear Sclerosis Indicator, Worse Eye, M, M	10			

Posterior Subcapsular Cataract Indicator, L, N, N	7			
Posterior Subcapsular Cataract Indicator, L, N, Y	3			
Posterior Subcapsular Cataract Indicator, L, N, M	0			
Posterior Subcapsular Cataract Indicator, L, Y, N	0			
Posterior Subcapsular Cataract Indicator, L, Y, Y	2			
Posterior Subcapsular Cataract Indicator, L, Y, M	3			
Posterior Subcapsular Cataract Indicator, L, M, N	1			
Posterior Subcapsular Cataract Indicator, L, M, Y	2			
Posterior Subcapsular Cataract Indicator, L, M, M	10			
Posterior Subcapsular Cataract Indicator, R, N, N	7			
Posterior Subcapsular Cataract Indicator, R, N, Y	1			
Posterior Subcapsular Cataract Indicator, R, N, M	0			
Posterior Subcapsular Cataract Indicator, R, Y, N	0			
Posterior Subcapsular Cataract Indicator, R, Y, Y	4			
Posterior Subcapsular Cataract Indicator, R, Y, M	3			
Posterior Subcapsular Cataract Indicator, R, M, N	1			
Posterior Subcapsular Cataract Indicator, R, M, Y	2			
Posterior Subcapsular Cataract Indicator, R, M, M	10			
Posterior Subcapsular Cataract Indicator, WE, N, N	6			
Posterior Subcapsular Cataract Indicator, WE, N, Y	3			
Posterior Subcapsular Cataract Indicator, WE, N, M	0			
Posterior Subcapsular Cataract Indicator, WE, Y, N	0			
Posterior Subcapsular Cataract Indicator, WE, Y, Y	4			
Posterior Subcapsular Cataract Indicator, WE, Y, M	3			
Posterior Subcapsular Cataract Indicator, WE, M, N	1			
Posterior Subcapsular Cataract Indicator, WE, M, Y	1			
Posterior Subcapsular Cataract Indicator, WE, M, M	10			
Pseudophakia, Left, No, No	11			
Pseudophakia, Left, No, Yes	3			
Pseudophakia, Left, No, Missing	3			
Pseudophakia, Left, Yes, No	1			
Pseudophakia, Left, Yes, Yes	10			
Pseudophakia, Left, Yes, Missing	0			
Pseudophakia, Left, Missing, No	0			

Pseudophakia, Left, Missing, Yes	0			
Pseudophakia, Left, Missing, Missing	0			
Pseudophakia, Right, No, No	12			
Pseudophakia, Right, No, Yes	2			
Pseudophakia, Right, No, Missing	3			
Pseudophakia, Right, Yes, No	1			
Pseudophakia, Right, Yes, Yes	10			
Pseudophakia, Right, Yes, Missing	0			
Pseudophakia, R, M, No	0			
Pseudophakia, R, M, Yes	0			
Pseudophakia, R, M, M	0			
Pseudophakia, Worse Eye, No, No	11			
Pseudophakia, Worse Eye, No, Yes	4			
Pseudophakia, Worse Eye, No, Missing	3			
Pseudophakia, Worse Eye, Yes, No	0			
Pseudophakia, Worse Eye, Yes, Yes	10			
Pseudophakia, Worse Eye, Yes, Missing	0			
Pseudophakia, Worse Eye, M, No	0			
Pseudophakia, Worse Eye, M, Yes	0			
Pseudophakia, Worse Eye, M, Missing	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Time to Best Response - All Treated Population

End point title	Part 2 - Time to Best Response - All Treated Population[49]

End point description:

Time to best response was defined as the time between the date of first dose and the first best documented response (PR or better) among participants who achieved a confirmed response of PR or better.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:Belantamab Mafodotin 2.5 mg/kg+Pembrolizumab 200mg			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Months				
median (full range (min-max))	1.7 (0.7 to 5.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Percentage of Participants With Clinical Benefit Rate - All Treated Population

End point title	Part 2 - Percentage of Participants With Clinical Benefit Rate - All Treated Population[50]

End point description:

Clinical benefit rate was defined as the percentage of participants with a confirmed minimal response (MR) or better according to the IMWG Response Criteria. MR is >= 25% but < 49% reduction of serum M-protein and reduction in 24-hour urinary M-protein by 50-89%.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Percentage of Participants				
number (confidence interval 95%)	43 (24.5 to 62.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Duration of Response - All Treated Population

End point title	Part 2 - Duration of Response - All Treated Population[51]

End point description:

Duration of response was defined as the time from first documented evidence of PR or better, to the time when disease progression (PD) is documented per IMWG response criteria; or death due to PD occurs among participants who achieve an overall response, i.e. confirmed PR or better. PD= Increase of 25% from lowest confirmed response value in 1 or more of the following criteria: Serum M-protein with absolute increase of >= 0.5 g/dL; Serum M-protein increase >= 1 g/dL if the lowest M-component was >=5 g/dL; Urinary M-protein (absolute increase must be >= 200 mg per 24 h). PR = ≥ 50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ≥ 90% or to <200 mg/24 h.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Months				
median (confidence interval 95%)	7.6 (1.4 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Progression-free Survival - All Treated Population

End point title	Part 2 - Progression-free Survival - All Treated Population[52]

End point description:

Progression-free survival was defined as the time from first dose until the earliest date of PD per IMWG response criteria, or death due to any cause. PD= Increase of 25% from lowest confirmed response value in 1 or more of the following criteria: Serum M-protein with absolute increase of >= 0.5 g/dL; Serum M-protein increase >= 1 g/dL if the lowest M-component was >=5 g/dL; Urinary M-protein (absolute increase must be >= 200 mg per 24 h).

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Months				
median (confidence interval 95%)	2.5 (0.8 to 5.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Time to Response - All Treated Population

End point title	Part 2 - Time to Response - All Treated Population[53]

End point description:

Time to response (TTR) was defined as the time between the date of first dose and the first documented evidence of response (PR or better) among participants who achieved a confirmed response of PR or better.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Months				
median (confidence interval 95%)	0.7 (0.7 to 1.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Maximum Concentration (Cmax) for Belantamab Mafodotin After First Dose - Pharmacokinetic (PK) Population

End point title	Part 1 - Maximum Concentration (Cmax) for Belantamab Mafodotin After First Dose - Pharmacokinetic (PK) Population[54]

End point description:

Blood samples were collected for Pharmacokinetic (PK) analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods. PK Population included participants in all treated population from whom at least one PK sample was obtained and analyzed for balintawak mafodotin.

End point type	Secondary

End point timeframe:

Pre-dose, end of infusion (EOI), 2, 4, 9, and 24 h post-SOI (start of infusion) on Cycle 1 Day 1, Cycle 1

Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[55]	0[56]		
Units: Microgram/millilitre (ug/mL)				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[55] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

[56] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Cmax for Belantamab Mafodotin After First Dose - PK Population

End point title	Part 2 - Cmax for Belantamab Mafodotin After First Dose - PK Population[57]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[58]			
Units: ug/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[58] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Overall Survival - All Treated Population

End point title	Part 2 - Overall Survival - All Treated Population[59]

End point description:

Overall Survival was defined as the time from first dose until death due to any cause. 99999=The upper limit of 95% CI was not estimate due to limited number of events

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Months				
median (confidence interval 95%)	99999 (19.1 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - End of Infusion Concentration (C-EOI) for Belantamab Mafodotin - PK Population

End point title	Part 1 - End of Infusion Concentration (C-EOI) for Belantamab Mafodotin - PK Population[60]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

EOI post belantamab mafodotin dose on Day 1 of each 21 day Cycle till Cycle 11

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[61]	0[62]		
Units: ug/mL				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[61] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

[62] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Time to Disease Progression - All Treated Population

End point title	Part 2 - Time to Disease Progression - All Treated Population[63]

End point description:

Time to disease progression was defined as the time from first dose until the earliest date of PD per IMWG response criteria, or death due to PD. PD= Increase of 25% from lowest confirmed response value in 1 or more of the following criteria: Serum M-protein with absolute increase of >= 0.5 g/dL; Serum M-protein increase >= 1 g/dL if the lowest M-component was >=5 g/dL; Urinary M-protein (absolute increase must be >= 200 mg per 24 h).

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[63] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Months				
median (confidence interval 95%)	2.5 (0.8 to 5.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Time of Cmax (Tmax) for Belantamab Mafodotin After First Dose - PK Population

End point title	Part 1 - Time of Cmax (Tmax) for Belantamab Mafodotin After First Dose - PK Population[64]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[65]	0[66]		
Units: Hour				
median (full range (min-max))	(to)	(to)		

Notes:

[65] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

[66] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - C-EOI for Belantamab Mafodotin - PK Population

End point title	Part 2 - C-EOI for Belantamab Mafodotin - PK Population[67]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

EOI post belantamab mafodotin dose on Day 1 of each 21 day Cycle till Cycle 11

Notes:

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[68]			
Units: ug/mL				
median (full range (min-max))	(to)			

Notes:

[68] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Trough Concentration Prior to the Next Dose for Each Cycle (Ctrough) for Belantamab Mafodotin - PK Population

End point title	Part 1 - Trough Concentration Prior to the Next Dose for Each Cycle (Ctrough) for Belantamab Mafodotin - PK Population[69]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose on Day 1 of each 21 day cycle from Cycle 1 until Cycle 13

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4 mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[70]	0[71]		
Units: ug/mL				
median (full range (min-max))	(to)	(to)		

Notes:

[70] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

[71] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Tmax for Belantamab Mafodotin After First Dose - PK Population

End point title	Part 2 - Tmax for Belantamab Mafodotin After First Dose - PK Population[72]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[73]			
Units: Hour				
median (full range (min-max))	(to)			

Notes:

[73] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Area Under Plasma Concentration-time Curve (AUC) From Time 0 to End of the Dosing Interval [AUC (0-tau)] for Belantamab Mafodotin After First Dose - PK Population

End point title	Part 1 - Area Under Plasma Concentration-time Curve (AUC) From Time 0 to End of the Dosing Interval [AUC (0-tau)] for Belantamab Mafodotin After First Dose - PK Population[74]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[75]	0[76]		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[75] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

[76] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Last Time Point Where the Concentration is Above the Limit of Quantification (Tlast) for Belantamab Mafodotin After First Dose - PK Population

End point title	Part 1 - Last Time Point Where the Concentration is Above the Limit of Quantification (Tlast) for Belantamab Mafodotin After First Dose - PK Population[77]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[77] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[78]	0[79]		
Units: Hour				
median (full range (min-max))	(to)	(to)		

Notes:

[78] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

[79] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Ctrough for Belantamab Mafodotin - PK Population

End point title	Part 2 - Ctrough for Belantamab Mafodotin - PK Population[80]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose on Day 1 of each 21 day cycle from Cycle 1 until Cycle 13

Notes:

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[81]			
Units: ug/mL				
median (full range (min-max))	(to)			

Notes:

[81] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Tlast for Belantamab Mafodotin After First Dose - PK Population

End point title	Part 2 - Tlast for Belantamab Mafodotin After First Dose - PK Population[82]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[83]			
Units: Hour				
median (full range (min-max))	(to)			

Notes:

[83] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - AUC (0-tau) for Belantamab Mafodotin After First Dose - PK Population

End point title	Part 2 - AUC (0-tau) for Belantamab Mafodotin After First Dose - PK Population[84]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5 mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[85]			
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[85] - Due to bioanalytical issues, PK data were not collected and analyzed for belantamab mafodotin.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - C-EOI for Total mAb - PK Population

End point title	Part 1 - C-EOI for Total mAb - PK Population[86]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		
Units: ug/mL				
median (full range (min-max))	40.15 (36.3 to 44.4)	65.30 (44.6 to 73.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Cmax for Total Monoclonal Antibody (mAb) After First Dose - PK Population

End point title	Part 1 - Cmax for Total Monoclonal Antibody (mAb) After First Dose - PK Population[87]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[87] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		

Units: ug/mL				
geometric mean (geometric coefficient of variation)	43.57 (± 7.1)	64.45 (± 21.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Cmax for Total mAb After First Dose - PK Population

End point title	Part 2 - Cmax for Total mAb After First Dose - PK Population[88]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4 and 24 h post-SOI on Cycle 1 Day 1

Notes:

[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: ug/mL				
geometric mean (geometric coefficient of variation)	46.70 (± 23.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Tmax for Total mAb After First Dose - PK Population

End point title	Part 1 - Tmax for Total mAb After First Dose - PK Population[89]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[89] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		
Units: Hour				
median (full range (min-max))	1.100 (0.53 to 2.18)	1.520 (0.75 to 2.05)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - C-EOI for Total mAb - PK Population

End point title	Part 2 - C-EOI for Total mAb - PK Population[90]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: ug/mL				
median (full range (min-max))	48.60 (17.4 to 68.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Tmax for Total mAb After First Dose - PK Population

End point title	Part 2 - Tmax for Total mAb After First Dose - PK Population[91]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[91] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Hour				
median (full range (min-max))	0.945 (0.47 to 2.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - AUC (0-tau) for Total mAb After First Dose - PK Population

End point title	Part 1 - AUC (0-tau) for Total mAb After First Dose - PK Population[92]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[92] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	4		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	6237.2 (± 17.9)	10817.8 (± 48.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Tlast for Total mAb After First Dose - PK Population

End point title	Part 2 - Tlast for Total mAb After First Dose - PK Population[93]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[93] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Hour				
median (full range (min-max))	503.140 (72.50 to 2060.68)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Last Time Point Where the Concentration is Above the Limit of Quantification (Tlast) for Total mAb After First Dose - PK Population

End point title	Part 1 - Last Time Point Where the Concentration is Above the Limit of Quantification (Tlast) for Total mAb After First Dose - PK Population[94]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[94] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	7		
Units: Hour				
median (full range (min-max))	501.800 (70.03 to 507.23)	481.580 (72.27 to 551.80)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Ctrough for Total mAb - PK Population

End point title	Part 1 - Ctrough for Total mAb - PK Population[95]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[95] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	4		
Units: ug/mL				
median (full range (min-max))	5.420 (3.85 to 7.87)	13.350 (1.83 to 13.50)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Ctrough for Total mAb - PK Population

End point title	Part 2 - Ctrough for Total mAb - PK Population[96]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[96] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: ug/mL				
median (full range (min-max))	7.735 (1.28 to 12.70)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Tmax for Cys-mcMMAF After First Dose - PK Population

End point title	Part 2 - Tmax for Cys-mcMMAF After First Dose - PK

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4 and 24 h post-SOI on Cycle 1 Day 1

Notes:

[97] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Hour				
median (full range (min-max))	23.580 (0.52 to 70.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Tmax for Cys-mcMMAF After First Dose - PK Population

End point title	Part 1 - Tmax for Cys-mcMMAF After First Dose - PK

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[98] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	5		

Units: Hour				
median (full range (min-max))	13.510 (4.05 to 22.97)	4.120 (0.57 to 73.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - C-EOI for Cys-mcMMAF After First Dose - PK Population

End point title	Part 2 - C-EOI for Cys-mcMMAF After First Dose - PK

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[99] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: ng/mL				
median (full range (min-max))	0.3150 (0.131 to 20.300)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - C-EOI for Cys-mcMMAF After First Dose - PK Population

End point title	Part 1 - C-EOI for Cys-mcMMAF After First Dose - PK

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[100] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	7		
Units: ng/mL				
median (full range (min-max))	0.7110 (0.342 to 1.080)	0.7630 (0.169 to 1.980)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Cmax for Cys-mcMMAF After First Dose - PK Population

End point title	Part 2 - Cmax for Cys-mcMMAF After First Dose - PK

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[101] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	1.2481 (± 111.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Cmax for Cysteine Maleimidocaproyl Monomethyl Auristatin F (Cys-mcMMAF) After First Dose - PK Population

End point title	Part 1 - Cmax for Cysteine Maleimidocaproyl Monomethyl Auristatin F (Cys-mcMMAF) After First Dose - PK Population[102]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[102] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	5		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	1.5799 (± 30.4)	1.0966 (± 40.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - AUC (0-tau) for Total mAb After First Dose - PK Population

End point title	Part 2 - AUC (0-tau) for Total mAb After First Dose - PK Population[103]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4 and 24 h post-SOI on Cycle 1 Day 1

Notes:

[103] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	7949.0 (± 27.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Tlast for Cys-mcMMAF After First Dose - PK Population

End point title	Part 1 - Tlast for Cys-mcMMAF After First Dose - PK

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[104] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Hour				
median (full range (min-max))	161.380 (70.03 to 168.13)	171.250 (72.27 to 501.28)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Tlast for Cys-mcMMAF After First Dose - PK Population

End point title	Part 2 - Tlast for Cys-mcMMAF After First Dose - PK

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[105] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Hour				
median (full range (min-max))	167.510 (23.90 to 503.15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Ctrough for Cys-mcMMAF - PK Population

End point title	Part 1 - Ctrough for Cys-mcMMAF - PK Population[106]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods. 00000 and 99999= Below the lower limit of quantification

End point type	Secondary

End point timeframe:

Pre-dose on Day 1 of each 21 day cycle from Cycle 1 until Cycle 19

Notes:

[106] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	6		
Units: ng/mL				
median (full range (min-max))				
Cycle 1 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)		
Cycle 4 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)		
Cycle 7 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)		
Cycle 10 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)		
Cycle 13 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)		
Cycle 16 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)		
Cycle 19 Day 1	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - AUC From Time 0 to 168 h After Dosing [AUC (0-168h)] for Cys-mcMMAF After First Dose - PK Population

End point title	Part 1 - AUC From Time 0 to 168 h After Dosing [AUC (0-168h)] for Cys-mcMMAF After First Dose - PK Population[107]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods. 99999 = geometric coefficient of variation could not be calculated for single participant

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[107] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	155.27 (± 99999)	90.61 (± 34.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Ctrough for Cys-mcMMAF - PK Population

End point title	Part 2 - Ctrough for Cys-mcMMAF - PK Population[108]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods. 00000 and 99999= Below the lower limit of quantification

End point type	Secondary

End point timeframe:

Pre-dose on Day 1 of each 21 day cycle from Cycle 1 until Cycle 13

Notes:

[108] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: ng/mL				
median (full range (min-max))				
Cycle 1 Day 1	00000 (00000 to 0.082)			
Cycle 4 Day 1	00000 (00000 to 0.344)			
Cycle 7 Day 1	99999 (99999 to 99999)			
Cycle 10 Day 1	00000 (00000 to 0.764)			
Cycle 13 Day 1	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Tmax for Pembrolizumab After First Dose - PK Population

End point title	Part 1 - Tmax for Pembrolizumab After First Dose - PK Population[109]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[109] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[110]	0[111]		
Units: Hour				
median (full range (min-max))	(to)	(to)		

Notes:

[110] - Pembrolizumab data were not collected and analyzed.

[111] - Pembrolizumab data were not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - AUC (0-168 h) for Cys-mcMMAF After First Dose - PK Population

End point title	Part 2 - AUC (0-168 h) for Cys-mcMMAF After First Dose - PK Population[112]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, and 24 h post-SOI on Cycle 1 Day 1

Notes:

[112] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	128.38 (± 70.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Cmax for Pembrolizumab After First Dose - PK Population

End point title	Part 1 - Cmax for Pembrolizumab After First Dose - PK Population[113]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[113] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[114]	0[115]		
Units: ug/mL				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[114] - Pembrolizumab data were not collected and analyzed.

[115] - Pembrolizumab data were not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Cmax for Pembrolizumab After First Dose - PK Population

End point title	Part 2 - Cmax for Pembrolizumab After First Dose - PK Population[116]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[116] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[117]			
Units: ug/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[117] - Pembrolizumab data were not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - AUC (0-tau) for Pembrolizumab After First Dose - PK Population

End point title	Part 1 - AUC (0-tau) for Pembrolizumab After First Dose - PK Population[118]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[118] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[119]	0[120]		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[119] - Pembrolizumab data were not collected and analyzed.

[120] - Pembrolizumab data were not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Tmax for Pembrolizumab After First Dose - PK Population

End point title	Part 2 - Tmax for Pembrolizumab After First Dose - PK Population[121]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[121] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[122]			
Units: Hour				
median (full range (min-max))	(to)			

Notes:

[122] - Pembrolizumab data were not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Belantamab Mafodotin - All Treated Population

End point title	Part 1 - Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Belantamab Mafodotin - All Treated Population[123]

End point description:

Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were tested in screening assay, and positive samples were further characterized for antibody titers. At the time of primary results posting, there was no participants with positive ADA results. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and until end of treatment (up to 178 weeks)

Notes:

[123] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		
Units: Participants				
Baseline	0	0		
End of Treatment	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - AUC (0-tau) for Pembrolizumab After First Dose - PK Population

End point title	Part 2 - AUC (0-tau) for Pembrolizumab After First Dose - PK Population[124]

End point description:

Blood samples were collected for PK analysis of belantamab mafodotin when administered intravenously in combination with pembrolizumab. Ctrough was calculated as the observed concentration at the end of a dosing interval, immediately before next study drug administration on Day 1 of each Cycle. PK

parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, EOI, 2, 4, 9, and 24 h post-SOI on Cycle 1 Day 1, Cycle 1 Day 4, Cycle 1 Day 8, and pre-dose on Cycle 2 Day 1

Notes:

[124] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[125]			
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[125] - Pembrolizumab data were not collected and analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Number of Participants With Post-baseline Positive ADAs Against Belantamab Mafodotin - All Treated Population

End point title	Part 2 - Number of Participants With Post-baseline Positive ADAs Against Belantamab Mafodotin - All Treated Population[126]

End point description:

Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were tested in screening assay, and positive samples were further characterized for antibody titers. At the time of primary results posting, there was no participants with positive ADA results. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and until end of treatment (up to 178 weeks)

Notes:

[126] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	27			

Units: Participants				
Baseline	0			
End of Treatment	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 - Titers of ADAs Against Belantamab Mafodotin - All Treated Population

End point title	Part 1 - Titers of ADAs Against Belantamab Mafodotin - All Treated Population[127]

End point description:

Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were to be further tested in screening assay, and positive samples were further to be characterized for antibody titers.

End point type	Secondary

End point timeframe:

Up to approximately 178 weeks

Notes:

[127] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[128]	0[129]		
Units: Participants				
number (not applicable)				

Notes:

[128] - There were no participants with positive ADA results. Hence the titer of ADA was not collected.

[129] - There were no participants with positive ADA results. Hence the titer of ADA was not collected.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2 - Titers of ADAs Against Belantamab Mafodotin - All Treated Population

End point title	Part 2 - Titers of ADAs Against Belantamab Mafodotin - All Treated Population[130]

End point description:

Serum samples collected for the analysis of the presence of ADAs using validated immunoassays. All samples were to be further tested in screening assay, and positive samples were further to be characterized for antibody titers.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 178 weeks

Notes:

[130] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoints are different for the different parts of the study. Hence, for any endpoint, results were presented either for Part 1 or Part 2 arms.

End point values	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg			
Subject group type	Reporting group			
Number of subjects analysed	0[131]			
Units: Participants				
number (not applicable)				

Notes:

[131] - There were no participants with positive ADA results. Hence the titer of ADA was not collected.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, non-serious adverse events (non-SAEs) and serious adverse events (SAEs) were collected from day 1 to week 178 for Main Study Phase and from week 178 to week 221 for PACT phase.

Adverse event reporting additional description:

All Treated Population included all participants who received at least one dose of study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mgEscalation

Reporting group description:

Participants were administered 2.5 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via intravenous (IV) infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal , or for a maximum of 35 cycles.

Reporting group title	PACT Phase- Belantamabmafodotin2.5mg/kg+Pembrolizumab 200 mg

Reporting group description:

Participants who completed approximately 178 weeks of treatment of 2.5 mg/kg belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion had the opportunity to continue receiving belantamab mafodotin in the PACT phase up to approximately 221 weeks.

Reporting group title	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg

Reporting group description:

Participants were administered belantamab mafodotin with recommended phase 2 dose (RP2D) of 2.5 mg/kg in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.

Reporting group title	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mgEscalation

Reporting group description:

Participants were administered with 3.4 mg/kg of belantamab mafodotin in combination with 200 mg of pembrolizumab via IV infusion on Day 1 of each 21-day Cycle up to until disease progression, intolerable toxicity, informed consent withdrawal, or for a maximum of 35 cycles.

Serious adverse events	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg Escalation	PACT Phase- Belantamabmafodotin2.5mg/kg+Pembrolizumab 200 mg	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	0 / 2 (0.00%)	5 / 28 (17.86%)
number of deaths (all causes)	2	0	7
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			

subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmacytoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiopulmonary failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Large intestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leishmaniasis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	4 / 28 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mg Escalation		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)		
number of deaths (all causes)	3		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasmacytoma			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cytokine release syndrome			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Platelet count decreased			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiopulmonary failure			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal disorders			
Large intestinal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leishmaniasis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia haemophilus			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part1:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg Escalation	PACT Phase-Belantamabmafodotin2.5mg/kg+Pembrolizumab 200 mg	Part2:BelantamabMafodotin2.5mg/kg+Pembrolizumab200mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	0 / 2 (0.00%)	27 / 28 (96.43%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	1	0	2
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	10 / 28 (35.71%)
occurrences (all)	1	0	12
Fatigue			

subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	3 / 28 (10.71%)
occurrences (all)	9	0	3
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	1	0	2
Epistaxis			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	3	0	3
Cough			
subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	3	0	3
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	2
Investigations			
Visual acuity tests abnormal			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences (all)	2	0	5
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	4 / 28 (14.29%)
occurrences (all)	2	0	4
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	3 / 28 (10.71%)
occurrences (all)	1	0	3
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	7 / 28 (25.00%)
occurrences (all)	2	0	7
Nervous system disorders			

Headache			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences (all)	3	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 6 (66.67%)	0 / 2 (0.00%)	5 / 28 (17.86%)
occurrences (all)	5	0	5
Neutropenia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	3	0	5
Thrombocytopenia			
subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	9 / 28 (32.14%)
occurrences (all)	4	0	10
Eye disorders			
Vision blurred			
subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	10 / 28 (35.71%)
occurrences (all)	4	0	10
Photophobia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	3 / 28 (10.71%)
occurrences (all)	2	0	3
Blepharitis			
subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences (all)	7	0	0
Dry eye			
subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	4 / 28 (14.29%)
occurrences (all)	4	0	4
Eye pruritus			
subjects affected / exposed	2 / 6 (33.33%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences (all)	2	0	0
Keratopathy			
subjects affected / exposed	6 / 6 (100.00%)	0 / 2 (0.00%)	20 / 28 (71.43%)
occurrences (all)	7	0	27
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	3 / 28 (10.71%)
occurrences (all)	0	0	3
Nausea			

subjects affected / exposed	3 / 6 (50.00%)	0 / 2 (0.00%)	7 / 28 (25.00%)
occurrences (all)	3	0	7
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	1	0	2
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	1	0	2
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	2	0	4
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	2
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	3 / 28 (10.71%)
occurrences (all)	0	0	3
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	0 / 28 (0.00%)
occurrences (all)	3	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	2 / 28 (7.14%)
occurrences (all)	1	0	2

Non-serious adverse events	Part1:BelantamabMafodotin3.4mg/kg+Pembrolizumab200mg Escalation		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 7 (57.14%)		
occurrences (all)	4		
Fatigue			
subjects affected / exposed	3 / 7 (42.86%)		
occurrences (all)	5		
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Investigations			
Visual acuity tests abnormal			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	2		
Aspartate aminotransferase increased			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Weight decreased subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2		
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3		
Neutropenia subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 4		
Thrombocytopenia subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 6		
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2		
Photophobia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1		
Blepharitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		

Dry eye subjects affected / exposed occurrences (all) Eye pruritus subjects affected / exposed occurrences (all) Keratopathy subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2 1 / 7 (14.29%) 1 6 / 7 (85.71%) 7		
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1 1 / 7 (14.29%) 2 1 / 7 (14.29%) 1 1 / 7 (14.29%) 2		
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all) Musculoskeletal chest pain subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0 1 / 7 (14.29%) 1 1 / 7 (14.29%) 1		

Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all) Pneumonia subjects affected / exposed occurrences (all)	 2 / 7 (28.57%) 2 1 / 7 (14.29%) 1		
Metabolism and nutrition disorders Hypomagnesaemia subjects affected / exposed occurrences (all) Hypokalaemia subjects affected / exposed occurrences (all)	 2 / 7 (28.57%) 2 1 / 7 (14.29%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 September 2018	The statistical model in dose escalation was revised from Bayesian Logistic Regression Model to mTPI and the overall sample size and related analytical methods had been changed. Part 2 stopping criteria had been added for continuous safety monitoring
26 February 2020	The protocol had been amended to address feedback from regulatory agencies, inclusions of items noted in protocol clarification letters, revisions due to discrepancies, revision of study drug related language, and other clarifications. DLT evaluable population was included to analysis population to further define Part 1 population.
27 August 2021	The protocol had been amended to update pembrolizumab safety, ECI overdose language, and standard text based on latest IB update for pembrolizumab (2021) and belantamab mafodotin (2021). Added the primary analysis at approximately 15 months follow-up from LSLV. Updated the planned derived PK parameters and PK/PD analyses, updated the data monitoring language, medical monitoring information, and SAE reporting.
21 February 2022	The protocol had been amended to provide updates including the addition of the end of study definition section and continued access to study intervention after the end of the study section (Post Analysis Continued Treatment [PACT]).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported