Clinical trial results:
A Phase I/II, Open-label, Dose Escalation and Expansion Study to Evaluate Safety, Tolerability, and Clinical Activity of the Antibody-Drug Conjugate GSK2857916 Administered in Combination with Lenalidomide Plus Dexamethasone (Arm A), or Bortezomib Plus Dexamethasone (Arm B) in Participants with Relapsed / Refractory Multiple Myeloma – dreaMM 6

Summary

EudraCT number	2017-004689-93
Trial protocol	GB ES
Global end of trial date	

Results information

Result version number	v1
This version publication date	15 March 2024
First version publication date	15 March 2024

Trial information

Trial identification

Sponsor protocol code	207497

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03544281
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	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	05 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 February 2023
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

Part 1 - To determine safety, tolerability, and to determine the RP2D dose of GSK2857916 administered in combination with either Len/Dex (Arm A) or Bor/Dex (Arm B) in subjects with RRMM.
Part 2 - To assess the clinical activity after treatment with the RP2D of GSK2857916 administered in combination with Len/Dex (Treatment A) or Bor/Dex (Treatment B) in subjects with RRMM.

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 September 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 79
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	United Kingdom: 29
Country: Number of subjects enrolled	United States: 29
Country: Number of subjects enrolled	Canada: 1
Worldwide total number of subjects	153
EEA total number of subjects	15

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)	59
From 65 to 84 years	94

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Safety data collection is still ongoing and additional results will be provided after study completion.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex

Arm description:

Participants with Relapsed or Refractory Multiple Myeloma (RRMM) received belantamab mafodotin as 1.9 milligram (mg)/kilogram (kg) dose on Day 1 of every alternate 28-day cycles (C1, C3, C5, C7 and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg per oral (PO) on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ intravenously (IV) on Days 1, 8, 15 and 22 of each cycle.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Participants with Relapsed or Refractory Multiple Myeloma (RRMM) received belantamab mafodotin intravenous (IV) solution as 1.9 milligram (mg)/kilogram (kg) dose on Day 1 of every alternate 28-day cycles (C1, C3, C5, C7 and so on) as a 30-60 minute infusion. Along with 25 mg or 10 mg Lenalidomide capsule orally on Days 1-21 of each 28 day cycle with 40 mg Dexamethasone tablet weekly per oral (PO)/ Dexamethasone Sodium Phosphate Injection (USP) as IV on Days 1, 8, 15, & 22 of each cycle

Arm title	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Injection, Infusion
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Arm title	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg dose on Day 1 and a 1.25 mg/kg dose on Day 8 of each 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg dose on Day 1 and a 1.25 mg/kg dose on Day 8 of each 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Arm title	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Arm title	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as 1.9 mg/kg dose on Day 1 of every alternate 21-day cycle (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 subcutaneously (SC) /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use, Subcutaneous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as 1.9 mg/kg dose on Day 1 of every alternate 21-day cycle (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 subcutaneously (SC) /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm title	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on

Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use, Subcutaneous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm title	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on cycle 1 day 1 (C1D1) followed by 1.9 mg/kg step-down dose on Day 1 of every alternate 21-day cycles C3 onwards (C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use, Subcutaneous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on cycle 1 day 1 (C1D1) followed by 1.9 mg/kg step-down dose on Day 1 of every alternate 21-day cycles C3 onwards (C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm title	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on Day 1 of every alternate 21-day cycles (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use, Subcutaneous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on Day 1 of every alternate 21-day cycles (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm title	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg on Day 1 and 1.25 mg/kg dose on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental

Investigational medicinal product name	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use, Subcutaneous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg on Day 1 and 1.25 mg/kg dose on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm title	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use, Subcutaneous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm title	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 3.4 mg/kg dose as a 1.7 mg/kg dose on Day 1 and 1.7 mg/kg on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental
Investigational medicinal product name	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Intravenous use, Oral use, Subcutaneous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 3.4 mg/kg dose as a 1.7 mg/kg dose on Day 1 and 1.7 mg/kg on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm title	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex

Arm description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 3.4 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Arm type	Experimental

Investigational medicinal product name	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion, Capsule, Injection
Routes of administration	Oral use, Subcutaneous use, Intravenous use

Dosage and administration details:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 3.4 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Number of subjects in period 1[1]	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex
Started	12	4	13
Completed	0	0	0
Not completed	12	4	13
Adverse event, serious fatal	3	2	6
Consent withdrawn by subject	2	-	1
Physician decision	-	-	-
Ongoing	7	2	6
Investigator Site Closed	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1[1]	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex
Started	16	12	12
Completed	0	0	0
Not completed	16	12	12
Adverse event, serious fatal	8	4	2
Consent withdrawn by subject	2	-	-
Physician decision	-	-	-
Ongoing	6	8	10
Investigator Site Closed	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1[1]	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex
Started	12	12	13
Completed	0	0	0
Not completed	12	12	13
Adverse event, serious fatal	4	5	5
Consent withdrawn by subject	-	-	2

Physician decision	-	1	-
Ongoing	8	6	6
Investigator Site Closed	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1[1]	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Started	18	12	16
Completed	0	0	0
Not completed	18	12	16
Adverse event, serious fatal	8	6	4
Consent withdrawn by subject	3	-	4
Physician decision	-	-	-
Ongoing	6	5	8
Investigator Site Closed	1	-	-
Lost to follow-up	-	1	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Worldwide 153 participants were enrolled, whereas 152 participants were actually received the study treatment

Reporting groups

Reporting group title	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex

Reporting group description:

Participants with Relapsed or Refractory Multiple Myeloma (RRMM) received belantamab mafodotin as 1.9 milligram (mg)/kilogram (kg) dose on Day 1 of every alternate 28-day cycles (C1, C3, C5, C7 and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg per oral (PO) on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ intravenously (IV) on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg dose on Day 1 and a 1.25 mg/kg dose on Day 8 of each 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 1.9 mg/kg dose on Day 1 of every alternate 21-day cycle (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 subcutaneously (SC) /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on cycle 1 day 1 (C1D1) followed by 1.9 mg/kg step-down dose on Day 1 of every alternate 21-day cycles C3 onwards (C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on Day 1 of every alternate 21-day cycles (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg on Day 1 and 1.25 mg/kg dose on Day 8 of every 21-day cycle as a 30-60 minute

infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 3.4 mg/kg dose as a 1.7 mg/kg dose on Day 1 and 1.7 mg/kg on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 3.4 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex
Number of subjects	12	4	13
Age Categorical Units: Participants			
18 to <65 years	4	3	4
65 to <75 years	5	1	8
>=75 years	3	0	1
Sex: Female, Male Units: Participants			
Male	10	4	8
Female	2	0	5
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	0	0	0
Asian - Central/South Asian Heritage	0	0	0
Asian - East Asian Heritage	0	0	0
Asian - South East Asian Heritage	0	0	0
Native Hawaiian or Other Pacific Islander	1	0	0
White - Arabic/North African Heritage	0	0	0
White - White/Caucasian/European Heritage	11	4	13
Missing	0	0	0

Reporting group values	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex
Number of subjects	16	12	12

Age Categorical Units: Participants			
18 to <65 years	4	6	3
65 to <75 years	8	3	8
>=75 years	4	3	1
Sex: Female, Male Units: Participants			
Male	13	7	9
Female	3	5	3
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	1	0	0
Asian - Central/South Asian Heritage	1	0	0
Asian - East Asian Heritage	0	0	0
Asian - South East Asian Heritage	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
White - Arabic/North African Heritage	1	0	0
White - White/Caucasian/European Heritage	13	11	11
Missing	0	0	1

Reporting group values	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex
Number of subjects	12	12	13
Age Categorical Units: Participants			
18 to <65 years	4	4	5
65 to <75 years	7	4	5
>=75 years	1	4	3
Sex: Female, Male Units: Participants			
Male	7	5	11
Female	5	7	2
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	1	3	0
Asian - Central/South Asian Heritage	0	0	0
Asian - East Asian Heritage	0	1	0
Asian - South East Asian Heritage	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	1
White - Arabic/North African Heritage	0	1	0
White - White/Caucasian/European Heritage	10	7	11
Missing	1	0	1

Reporting group values	Belantamab mafodotin 2.5 mg/kg SINGLE +	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE +

	Bor/Dex		Bor/Dex
Number of subjects	18	12	16
Age Categorical Units: Participants			
18 to <65 years	6	6	9
65 to <75 years	8	5	5
>=75 years	4	1	2
Sex: Female, Male Units: Participants			
Male	11	8	11
Female	7	4	5
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	4	0	1
Asian - Central/South Asian Heritage	1	0	0
Asian - East Asian Heritage	0	0	0
Asian - South East Asian Heritage	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White - Arabic/North African Heritage	0	1	0
White - White/Caucasian/European Heritage	12	11	15
Missing	0	0	0

Reporting group values	Total		
Number of subjects	152		
Age Categorical Units: Participants			
18 to <65 years	58		
65 to <75 years	67		
>=75 years	27		
Sex: Female, Male Units: Participants			
Male	104		
Female	48		
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	10		
Asian - Central/South Asian Heritage	2		
Asian - East Asian Heritage	1		
Asian - South East Asian Heritage	2		
Native Hawaiian or Other Pacific Islander	2		
White - Arabic/North African Heritage	3		
White - White/Caucasian/European Heritage	129		
Missing	3		

End points reporting groups

Reporting group title	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex

Reporting group description:

Participants with Relapsed or Refractory Multiple Myeloma (RRMM) received belantamab mafodotin as 1.9 milligram (mg)/kilogram (kg) dose on Day 1 of every alternate 28-day cycles (C1, C3, C5, C7 and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg per oral (PO) on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ intravenously (IV) on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg dose on Day 1 and a 1.25 mg/kg dose on Day 8 of each 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 1.9 mg/kg dose on Day 1 of every alternate 21-day cycle (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 subcutaneously (SC) /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on cycle 1 day 1 (C1D1) followed by 1.9 mg/kg step-down dose on Day 1 of every alternate 21-day cycles C3 onwards (C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on Day 1 of every alternate 21-day cycles (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg on Day 1 and 1.25 mg/kg dose on Day 8 of every 21-day cycle as a 30-60 minute

infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 3.4 mg/kg dose as a 1.7 mg/kg dose on Day 1 and 1.7 mg/kg on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 3.4 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Primary: Number of participants with DLTs, Treatment B - DLT-evaluable population

End point title	Number of participants with DLTs, Treatment B - DLT-evaluable population[1][2]

End point description:

DLT is an adverse event (AE) that is considered by the investigator to be clinically relevant and attributed to the study therapy during the 21 day DLT period and meets at least one of the DLT criteria: Grade 3 or greater febrile neutropenia lasting >48 hours (h) despite adequate treatment; Grade 4 thrombocytopenia <25,000/mm^3 accompanied by significant bleeding; any Grade 3 or greater non-hematologic laboratory value (if laboratory abnormality persist >48 h despite supportive treatment or abnormality leading to hospitalisation); non-hematologic toxicity which does not resolve with appropriate supportive treatment within 48 h, Grade 4 corneal adverse events; and other organ specific toxicities (liver toxicity that causes discontinuation of treatment). DLT-evaluable population included participants who received at least 1 full dose of belantamab mafodotin and ≥75% of planned doses of Bor/Dex by the end of Cycle 1 (Day 21).

End point type	Primary

End point timeframe:

Up to 21 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.
[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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex		
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: Number of participants with dose limiting toxicities (DLTs), Treatment A - DLT-evaluable population

End point title	Number of participants with dose limiting toxicities (DLTs), Treatment A - DLT-evaluable population[3][4]

End point description:

DLT is an adverse event (AE) that is considered by the investigator to be clinically relevant and attributed to the study therapy during the 28 day DLT period and meets at least one of the DLT criteria: Grade 3 or greater febrile neutropenia lasting >48 hours (h) despite adequate treatment; Grade 4 thrombocytopenia <25,000/mm^3 accompanied by significant bleeding; any Grade 3 or greater non-hematologic laboratory value (if laboratory abnormality persist >48 h despite supportive treatment or abnormality leading to hospitalisation); non-hematologic toxicity which does not resolve with appropriate supportive treatment within 48 h, Grade 4 corneal adverse events; and other organ specific toxicities (liver toxicity that causes discontinuation of treatment). DLT-evaluable population included participants who received at least 1 full dose of belantamab mafodotin and at least 75% of planned doses of Len/Dex by the end of Cycle 1 (Day 28).

End point type	Primary

End point timeframe:

Up to 28 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.
[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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	6	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with adverse events (AEs) and serious adverse events (SAEs) - All treated population

End point title	Number of participants with adverse events (AEs) and serious adverse events (SAEs) - All treated population[5]

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. SAE is defined as any untoward medical occurrence that, at any dose results in death, Is life-threatening, Requires inpatient hospitalization or prolongation of existing hospitalization, Results in persistent disability/incapacity or Is a congenital anomaly/birth defect, Other situations which involve medical or scientific judgment or is associated with liver injury and impaired liver function. SAEs are subset of AEs. All treated population included participants who took at least 1 dose of any study treatment.

End point type	Primary

End point timeframe:

Up to approximately 4.5 years

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Any AE	12	4	13	16
Any SAE	6	2	6	10

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Any AE	12	12	12	12
Any SAE	8	8	6	6

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Any AE	13	18	12	16
Any SAE	7	13	6	9

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with Worst-Case Amount of Increase from Baseline Value in Corrected QT Interval Using Fredericia's Formula (QTcF) - All treated population

End point title	Number of participants with Worst-Case Amount of Increase from Baseline Value in Corrected QT Interval Using Fredericia's Formula (QTcF) - All treated population[6]

End point description:

12-lead electrocardiogram (ECGs) were obtained using an automated electrocardiogram (ECG) machine that automatically calculated the QTcF intervals. QTc values are categorized into the clinical concern ranges which are specific to changes in QTc: 31-60 milliseconds (msec), and >60 msec, and >530msec. An increase is defined relative to Baseline. Baseline (Day 1) was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Data of number of participants with worst-case increase post baseline is presented.

End point type	Primary

End point timeframe:

Up to approximately 4.5 years

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Increase of 31-60 msec	3	3	5	3
Increase of >60 msec	0	0	3	2
Increase of >530 msec	0	0	0	0

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	12	12	12
Units: Participants				
Increase of 31-60 msec	1	3	1	2
Increase of >60 msec	0	0	0	0
Increase of >530 msec	0	0	0	0

End point values	Belantamab mafodotin 2.5	Belantamab mafodotin 2.5	Belantamab mafodotin 3.4	Belantamab mafodotin 3.4

	mg/kg SPLIT + Bor/Dex	mg/kg SINGLE + Bor/Dex	mg/kg SPLIT + Bor/Dex	mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Increase of 31-60 msec	5	4	5	5
Increase of >60 msec	1	2	0	0
Increase of >530 msec	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Worst-case Grade Change From Baseline in Hematology Parameters - All treated population

End point title	Number of Participants With Worst-case Grade Change From Baseline in Hematology Parameters - All treated population[7]

End point description:

Blood samples were collected for analysis of following hematology parameters: Hemoglobin (hemoglobin increased and anemia), Lymphocytes (lymphocyte count increased and lymphocyte count decreased), Neutrophils, Platelets and Leukocytes (leukocytosis and white blood cells decreased). The laboratory parameters were graded according to Common Terminology Criteria for Adverse Events (CTCAE) version (v) 4.03. Grade (G) 1: mild; G2: moderate; G3: severe or medically significant; G4: life-threatening consequences. Higher grade indicates greater severity and increase in grade was defined relative to Baseline grade. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Any worst-case post baseline increases in grade along with any increase to a maximum G3 and a maximum G4 are presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Hemoglobin increased, Any Grade Increase	0	0	0	0
Hemoglobin increased, Increase to Grade 3	0	0	0	0
Hemoglobin increased, Increase to Grade 4	0	0	0	0
Anemia, Any Grade Increase	7	2	8	9
Anemia, Increase to Grade 3	0	0	3	2
Anemia, Increase to Grade 4	0	0	0	0
Lymphocyte count increased, Any Grade Increase	0	1	0	0

Lymphocyte count increased, Increase to Grade 3	0	0	0	0
Lymphocyte count increased, Increase to Grade 4	0	0	0	0
Lymphocyte count decreased, Any Grade Increase	11	3	10	12
Lymphocyte count decreased, Increase to Grade 3	7	1	3	4
Lymphocyte count decreased, Increase to Grade 4	0	0	1	3
Neutrophils, Any Grade Increase	8	3	9	9
Neutrophils, Increase to Grade 3	3	2	4	4
Neutrophils, Increase to Grade 4	0	0	1	1
Platelets, Any Grade Increase	9	4	12	15
Platelets, Increase to Grade 3	1	1	4	5
Platelets, Increase to Grade 4	1	0	2	1
Leukocytosis, Any Grade Increase	0	0	0	0
Leukocytosis, Increase to Grade 3	0	0	0	0
Leukocytosis, Increase to Grade 4	0	0	0	0
White blood cell decreased, Any Grade Increase	10	3	11	8
White blood cell decreased, Increase to Grade 3	2	0	1	3
White blood cell decreased, Increase to Grade 4	0	0	0	2

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Hemoglobin increased, Any Grade Increase	0	0	1	0
Hemoglobin increased, Increase to Grade 3	0	0	0	0
Hemoglobin increased, Increase to Grade 4	0	0	0	0
Anemia, Any Grade Increase	5	6	2	3
Anemia, Increase to Grade 3	2	2	1	2
Anemia, Increase to Grade 4	0	0	0	0
Lymphocyte count increased, Any Grade Increase	2	2	0	0
Lymphocyte count increased, Increase to Grade 3	0	0	0	0
Lymphocyte count increased, Increase to Grade 4	0	0	0	0
Lymphocyte count decreased, Any Grade Increase	11	12	10	11
Lymphocyte count decreased, Increase to Grade 3	5	6	3	5
Lymphocyte count decreased, Increase to Grade 4	1	3	2	1

Neutrophils, Any Grade Increase	6	6	5	4
Neutrophils, Increase to Grade 3	1	3	3	1
Neutrophils, Increase to Grade 4	0	1	0	0
Platelets, Any Grade Increase	11	12	11	12
Platelets, Increase to Grade 3	3	2	4	3
Platelets, Increase to Grade 4	7	9	5	6
Leukocytosis, Any Grade Increase	0	0	0	0
Leukocytosis, Increase to Grade 3	0	0	0	0
Leukocytosis, Increase to Grade 4	0	0	0	0
White blood cell decreased, Any Grade Increase	5	8	3	7
White blood cell decreased, Increase to Grade 3	1	2	1	0
White blood cell decreased, Increase to Grade 4	0	0	0	0

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Hemoglobin increased, Any Grade Increase	0	1	0	1
Hemoglobin increased, Increase to Grade 3	0	0	0	0
Hemoglobin increased, Increase to Grade 4	0	0	0	0
Anemia, Any Grade Increase	9	11	8	10
Anemia, Increase to Grade 3	5	2	2	3
Anemia, Increase to Grade 4	0	0	0	0
Lymphocyte count increased, Any Grade Increase	0	0	0	1
Lymphocyte count increased, Increase to Grade 3	0	0	0	0
Lymphocyte count increased, Increase to Grade 4	0	0	0	0
Lymphocyte count decreased, Any Grade Increase	12	13	10	15
Lymphocyte count decreased, Increase to Grade 3	6	6	3	8
Lymphocyte count decreased, Increase to Grade 4	3	2	3	1
Neutrophils, Any Grade Increase	7	10	8	9
Neutrophils, Increase to Grade 3	3	1	4	2
Neutrophils, Increase to Grade 4	1	3	0	0
Platelets, Any Grade Increase	13	18	12	16
Platelets, Increase to Grade 3	5	3	2	3
Platelets, Increase to Grade 4	6	9	9	10
Leukocytosis, Any Grade Increase	0	0	0	0
Leukocytosis, Increase to Grade 3	0	0	0	0
Leukocytosis, Increase to Grade 4	0	0	0	0

White blood cell decreased, Any Grade Increase	8	11	8	13
White blood cell decreased, Increase to Grade 3	2	3	3	0
White blood cell decreased, Increase to Grade 4	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Worst-case Change Post-baseline in Hematology Parameters - All treated population

End point title	Number of Participants With Worst-case Change Post-baseline in Hematology Parameters - All treated population[8]

End point description:

Blood samples were collected for the analysis of following hematology parameters: basophils, eosinophils, hematocrit, mean corpuscular hemoglobin concentration (MCHC), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), monocytes, erythrocytes 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 from baseline have been presented. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Basophils, Decrease to Low	0	0	0	0
Basophils, Change to Normal or No Change	10	4	10	10
Basophils, Increase to High	2	0	3	4
Eosinophils, Decrease to Low	2	1	4	2
Eosinophils, Change to Normal or No Change	7	2	8	7
Eosinophils, Increase to High	3	2	3	6
Hematocrit, Decrease to Low	4	1	1	4
Hematocrit, Change to Normal or No Change	8	3	12	12
Hematocrit, Increase to High	1	0	0	0
MCH, Decrease to Low	0	0	3	1
MCH, Change to Normal or No Change	9	3	7	13
MCH, Increase to High	3	1	3	2

MCHC, Decrease to Low	4	0	4	4
MCHC, Change to Normal or No Change	8	3	9	12
MCHC, Increase to High	0	1	1	0
MCV, Decrease to Low	0	0	4	1
MCV, Change to Normal or No Change	10	3	7	11
MCV, Increase to High	2	1	3	4
Monocytes, Decrease to Low	5	1	4	3
Monocytes, Change to Normal or No Change	4	2	2	4
Monocytes, Increase to High	4	2	11	10
Erythrocytes, Decrease to Low	2	1	0	1
Erythrocytes, Change to Normal or No Change	9	3	13	13
Erythrocytes, Increase to High	1	0	0	2
Reticulocytes, Decrease to Low	3	1	2	4
Reticulocytes, Change to Normal or No Change	7	1	5	7
Reticulocytes, Increase to High	3	2	7	6

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Basophils, Decrease to Low	1	1	0	0
Basophils, Change to Normal or No Change	9	10	10	11
Basophils, Increase to High	2	1	2	1
Eosinophils, Decrease to Low	1	3	0	2
Eosinophils, Change to Normal or No Change	11	9	12	10
Eosinophils, Increase to High	0	0	0	1
Hematocrit, Decrease to Low	2	5	1	1
Hematocrit, Change to Normal or No Change	10	7	9	11
Hematocrit, Increase to High	0	1	2	0
MCH, Decrease to Low	0	3	1	3
MCH, Change to Normal or No Change	10	7	8	9
MCH, Increase to High	2	3	3	0
MCHC, Decrease to Low	2	6	5	6
MCHC, Change to Normal or No Change	8	6	6	6
MCHC, Increase to High	2	1	1	0
MCV, Decrease to Low	0	2	1	2
MCV, Change to Normal or No Change	10	7	7	10
MCV, Increase to High	2	3	5	1
Monocytes, Decrease to Low	5	4	7	8
Monocytes, Change to Normal or No Change	3	1	1	1
Monocytes, Increase to High	6	10	10	8

Erythrocytes, Decrease to Low	0	2	0	0
Erythrocytes, Change to Normal or No Change	11	10	12	11
Erythrocytes, Increase to High	1	1	0	1
Reticulocytes, Decrease to Low	1	1	2	4
Reticulocytes, Change to Normal or No Change	9	6	5	2
Reticulocytes, Increase to High	2	6	7	8

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Basophils, Decrease to Low	0	1	0	2
Basophils, Change to Normal or No Change	11	12	11	12
Basophils, Increase to High	2	2	1	1
Eosinophils, Decrease to Low	3	2	1	2
Eosinophils, Change to Normal or No Change	10	11	10	13
Eosinophils, Increase to High	0	3	1	0
Hematocrit, Decrease to Low	3	3	1	7
Hematocrit, Change to Normal or No Change	10	14	11	8
Hematocrit, Increase to High	0	1	0	1
MCH, Decrease to Low	2	6	2	1
MCH, Change to Normal or No Change	10	9	10	11
MCH, Increase to High	1	4	0	4
MCHC, Decrease to Low	6	7	5	5
MCHC, Change to Normal or No Change	6	10	6	11
MCHC, Increase to High	1	2	1	0
MCV, Decrease to Low	0	4	0	0
MCV, Change to Normal or No Change	11	10	10	13
MCV, Increase to High	2	4	2	3
Monocytes, Decrease to Low	5	7	3	5
Monocytes, Change to Normal or No Change	2	3	5	4
Monocytes, Increase to High	8	10	5	8
Erythrocytes, Decrease to Low	0	4	2	3
Erythrocytes, Change to Normal or No Change	13	14	9	13
Erythrocytes, Increase to High	0	0	1	0
Reticulocytes, Decrease to Low	2	4	3	5
Reticulocytes, Change to Normal or No Change	8	6	4	2
Reticulocytes, Increase to High	3	9	6	10

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Worst-case Grade Change From Baseline in Clinical Chemistry Parameters - All treated population

End point title	Number of Participants With Worst-case Grade Change From Baseline in Clinical Chemistry Parameters - All treated population[9]

End point description:

Blood samples were collected for analysis of following clinical chemistry parameters: Hyperglycemia, Hypoglycemia, Albumin, Alkaline Phosphatase, Alanine Aminotransferase (ALT), Aspartate Aminotransferase, (AST), Bilirubin, Creatine Kinase (CK), Creatinine, Gamma Glutamyl Transferase (GGT), Hyperkalemia, Hypokalemia, Hypermagnesemia, Hypomagnesemia, Phosphate, Hypernatremia, Hyponatremia, Urate, Hypercalcemia and Hypocalcemia. Laboratory parameters were graded according to CTCAE v4.03. Grade (G) 1: mild; G2: moderate; G3: severe or medically significant; G4: life-threatening consequences. Higher grade indicates greater severity and increase in grade was defined relative to Baseline grade. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Any worst-case post baseline increases in grade along with any increase to a maximum G3 and a maximum G4 are presented.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Hyperglycemia, Any Grade Increase	3	1	9	11
Hyperglycemia, Increase to Grade 3	0	0	0	1
Hyperglycemia, Increase to Grade 4	0	0	0	1
Hypoglycemia, Any Grade Increase	2	0	1	1
Hypoglycemia, Increase to Grade 3	0	0	0	0
Hypoglycemia, Increase to Grade 4	0	0	0	0
Albumin, Any Grade Increase	6	2	8	9
Albumin, Increase to Grade 3	0	0	0	0
Albumin, Increase to Grade 4	0	0	0	0
Alkaline Phosphatase, Any Grade Increase	4	0	7	6
Alkaline Phosphatase, Increase to Grade 3	0	0	0	0
Alkaline Phosphatase, Increase to Grade 4	0	0	0	0
ALT, Any Grade Increase	7	1	7	7
ALT, Increase to Grade 3	0	0	0	0
ALT, Increase to Grade 4	0	0	0	0
AST, Any Grade Increase	4	2	8	6
AST, Increase to Grade 3	0	0	0	0
AST, Increase to Grade 4	0	0	0	0

Bilirubin, Any Grade Increase	1	0	1	4
Bilirubin, Increase to Grade 3	0	0	0	0
Bilirubin, Increase to Grade 4	0	0	0	0
CK, Any Grade Increase	3	2	4	2
CK, Increase to Grade 3	1	0	0	0
CK, Increase to Grade 4	0	0	0	0
Creatinine, Any Grade Increase	1	0	7	2
Creatinine, Increase to Grade 3	0	0	0	0
Creatinine, Increase to Grade 4	0	0	0	0
GGT, Any Grade Increase	9	1	9	9
GGT, Increase to Grade 3	2	0	2	4
GGT, Increase to Grade 4	0	0	0	0
Hyperkalemia, Any Grade Increase	0	0	1	1
Hyperkalemia, Increase to Grade 3	0	0	0	0
Hyperkalemia, Increase to Grade 4	0	0	0	0
Hypokalemia, Any Grade Increase	3	2	3	4
Hypokalemia, Increase to Grade 3	1	0	2	2
Hypokalemia, Increase to Grade 4	0	0	0	0
Hypermagnesemia, Any Grade Increase	0	0	1	0
Hypermagnesemia, Increase to Grade 3	0	0	0	0
Hypermagnesemia, Increase to Grade 4	0	0	0	0
Hypomagnesemia, Any Grade Increase	3	2	3	4
Hypomagnesemia, Increase to Grade 3	0	0	0	0
Hypomagnesemia, Increase to Grade 4	0	0	0	0
Phosphate, Any Grade Increase	6	3	5	4
Phosphate, Increase to Grade 3	2	1	3	1
Phosphate, Increase to Grade 4	0	0	0	0
Hypernatremia, Any Grade Increase	1	0	1	1
Hypernatremia, Increase to Grade 3	0	0	0	0
Hypernatremia, Increase to Grade 4	0	0	0	0
Hyponatremia, Any Grade Increase	4	1	3	3
Hyponatremia, Increase to Grade 3	0	1	0	2
Hyponatremia, Increase to Grade 4	0	0	0	0
Urate, Any Grade Increase	1	0	1	1
Urate, Increase to Grade 3	0	0	0	0
Urate, Increase to Grade 4	1	0	1	1
Hypercalcemia, Any Grade Increase	0	0	2	1
Hypercalcemia, Increase to Grade 3	0	0	1	0
Hypercalcemia, Increase to Grade 4	0	0	0	0
Hypocalcemia, Any Grade Increase	5	0	4	2
Hypocalcemia, Increase to Grade 3	1	0	0	0
Hypocalcemia, Increase to Grade 4	3	0	2	1

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Hyperglycemia, Any Grade Increase	8	9	9	8
Hyperglycemia, Increase to Grade 3	0	0	3	1
Hyperglycemia, Increase to Grade 4	0	0	0	0
Hypoglycemia, Any Grade Increase	0	2	1	3
Hypoglycemia, Increase to Grade 3	0	0	0	1
Hypoglycemia, Increase to Grade 4	0	0	0	0
Albumin, Any Grade Increase	5	8	4	5
Albumin, Increase to Grade 3	0	2	0	2
Albumin, Increase to Grade 4	0	0	0	0
Alkaline Phosphatase, Any Grade Increase	6	4	5	6
Alkaline Phosphatase, Increase to Grade 3	0	0	0	0
Alkaline Phosphatase, Increase to Grade 4	0	0	0	0
ALT, Any Grade Increase	5	5	9	8
ALT, Increase to Grade 3	0	1	2	1
ALT, Increase to Grade 4	0	0	0	0
AST, Any Grade Increase	10	12	8	10
AST, Increase to Grade 3	0	1	1	3
AST, Increase to Grade 4	0	0	0	0
Bilirubin, Any Grade Increase	2	2	0	3
Bilirubin, Increase to Grade 3	0	0	0	0
Bilirubin, Increase to Grade 4	0	0	0	0
CK, Any Grade Increase	1	3	3	4
CK, Increase to Grade 3	0	0	0	1
CK, Increase to Grade 4	0	0	0	0
Creatinine, Any Grade Increase	2	2	6	2
Creatinine, Increase to Grade 3	0	0	0	0
Creatinine, Increase to Grade 4	0	0	0	0
GGT, Any Grade Increase	6	7	5	10
GGT, Increase to Grade 3	1	2	1	2
GGT, Increase to Grade 4	0	0	0	1
Hyperkalemia, Any Grade Increase	0	2	0	0
Hyperkalemia, Increase to Grade 3	0	0	0	0
Hyperkalemia, Increase to Grade 4	0	0	0	0
Hypokalemia, Any Grade Increase	6	4	8	3
Hypokalemia, Increase to Grade 3	0	1	0	0
Hypokalemia, Increase to Grade 4	0	0	0	0
Hypermagnesemia, Any Grade Increase	2	0	1	0
Hypermagnesemia, Increase to Grade 3	0	0	0	0
Hypermagnesemia, Increase to Grade 4	0	0	0	0
Hypomagnesemia, Any Grade Increase	3	2	0	1
Hypomagnesemia, Increase to Grade 3	0	0	0	0
Hypomagnesemia, Increase to Grade 4	0	0	0	0
Phosphate, Any Grade Increase	4	7	6	5
Phosphate, Increase to Grade 3	0	2	2	2
Phosphate, Increase to Grade 4	0	0	0	0
Hypernatremia, Any Grade Increase	1	2	4	2
Hypernatremia, Increase to Grade 3	0	0	0	0

Hypernatremia, Increase to Grade 4	0	0	0	0
Hyponatremia, Any Grade Increase	4	3	3	5
Hyponatremia, Increase to Grade 3	1	0	0	2
Hyponatremia, Increase to Grade 4	0	0	0	0
Urate, Any Grade Increase	1	1	0	1
Urate, Increase to Grade 3	0	0	0	0
Urate, Increase to Grade 4	1	1	0	1
Hypercalcemia, Any Grade Increase	2	2	2	1
Hypercalcemia, Increase to Grade 3	0	0	0	0
Hypercalcemia, Increase to Grade 4	0	0	0	0
Hypocalcemia, Any Grade Increase	1	3	2	2
Hypocalcemia, Increase to Grade 3	0	0	0	0
Hypocalcemia, Increase to Grade 4	0	1	0	1

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Hyperglycemia, Any Grade Increase	5	10	6	8
Hyperglycemia, Increase to Grade 3	1	1	0	1
Hyperglycemia, Increase to Grade 4	1	0	0	1
Hypoglycemia, Any Grade Increase	0	1	0	1
Hypoglycemia, Increase to Grade 3	0	0	0	0
Hypoglycemia, Increase to Grade 4	0	0	0	0
Albumin, Any Grade Increase	7	14	5	8
Albumin, Increase to Grade 3	2	0	0	0
Albumin, Increase to Grade 4	0	0	0	0
Alkaline Phosphatase, Any Grade Increase	8	8	2	5
Alkaline Phosphatase, Increase to Grade 3	0	0	0	0
Alkaline Phosphatase, Increase to Grade 4	0	0	0	0
ALT, Any Grade Increase	6	6	7	8
ALT, Increase to Grade 3	1	0	0	1
ALT, Increase to Grade 4	0	0	0	1
AST, Any Grade Increase	8	11	8	12
AST, Increase to Grade 3	1	0	0	0
AST, Increase to Grade 4	0	0	0	1
Bilirubin, Any Grade Increase	2	2	1	5
Bilirubin, Increase to Grade 3	0	0	0	1
Bilirubin, Increase to Grade 4	0	0	0	0
CK, Any Grade Increase	4	4	4	7
CK, Increase to Grade 3	1	0	0	0
CK, Increase to Grade 4	0	0	0	0
Creatinine, Any Grade Increase	4	3	1	6
Creatinine, Increase to Grade 3	0	0	0	0
Creatinine, Increase to Grade 4	0	0	0	0

GGT, Any Grade Increase	8	10	6	9
GGT, Increase to Grade 3	1	2	0	2
GGT, Increase to Grade 4	0	0	0	0
Hyperkalemia, Any Grade Increase	3	3	0	3
Hyperkalemia, Increase to Grade 3	0	0	0	0
Hyperkalemia, Increase to Grade 4	0	0	0	0
Hypokalemia, Any Grade Increase	4	6	7	4
Hypokalemia, Increase to Grade 3	0	0	0	1
Hypokalemia, Increase to Grade 4	0	0	0	0
Hypermagnesemia, Any Grade Increase	4	1	1	2
Hypermagnesemia, Increase to Grade 3	1	0	0	1
Hypermagnesemia, Increase to Grade 4	0	0	0	0
Hypomagnesemia, Any Grade Increase	1	7	4	4
Hypomagnesemia, Increase to Grade 3	0	0	0	0
Hypomagnesemia, Increase to Grade 4	0	0	0	0
Phosphate, Any Grade Increase	8	8	8	7
Phosphate, Increase to Grade 3	3	3	3	0
Phosphate, Increase to Grade 4	0	0	0	0
Hypernatremia, Any Grade Increase	1	1	1	2
Hypernatremia, Increase to Grade 3	0	0	0	0
Hypernatremia, Increase to Grade 4	0	0	0	0
Hyponatremia, Any Grade Increase	4	4	2	5
Hyponatremia, Increase to Grade 3	1	1	0	1
Hyponatremia, Increase to Grade 4	0	0	0	0
Urate, Any Grade Increase	0	0	0	1
Urate, Increase to Grade 3	0	0	0	0
Urate, Increase to Grade 4	0	0	0	1
Hypercalcemia, Any Grade Increase	3	4	1	1
Hypercalcemia, Increase to Grade 3	1	1	0	0
Hypercalcemia, Increase to Grade 4	0	1	0	0
Hypocalcemia, Any Grade Increase	5	1	0	3
Hypocalcemia, Increase to Grade 3	1	0	0	0
Hypocalcemia, Increase to Grade 4	2	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Worst-case Change Post-baseline in Clinical Chemistry Parameters - All treated population

End point title	Number of Participants With Worst-case Change Post-baseline in Clinical Chemistry Parameters - All treated population[10]

End point description:

Blood samples were collected for analysis of following clinical chemistry parameters: Direct Bilirubin (DB), Calcium, Chloride, Carbon Dioxide (CO2), lactate dehydrogenase (LDH) and Protein. 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 from baseline have been presented. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
DB, Decrease to Low	0	0	0	0
DB, Change to Normal or No Change	4	4	9	8
DB, Increase to High	6	0	4	5
Calcium, Decrease to Low	7	1	7	7
Calcium, Change to Normal or No Change	5	3	6	7
Calcium, Increase to High	0	0	1	1
Chloride, Decrease to Low	1	1	1	3
Chloride, Change to Normal or No Change	5	3	8	10
Chloride, Increase to High	5	0	4	2
CO2, Decrease to Low	5	0	5	5
CO2, Change to Normal or No Change	7	4	7	7
CO2, Increase to High	0	0	1	2
Protein, Decrease to Low	8	2	5	12
Protein, Change to Normal or No Change	4	2	8	3
Protein, Increase to High	0	0	0	1
LDH, Decrease to Low	0	0	2	2
LDH, Change to Normal or No Change	5	1	3	6
LDH, Increase to High	6	3	9	8

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
DB, Decrease to Low	0	0	0	0
DB, Change to Normal or No Change	11	8	10	9
DB, Increase to High	1	4	2	2
Calcium, Decrease to Low	2	6	4	2
Calcium, Change to Normal or No Change	8	5	6	10
Calcium, Increase to High	2	1	2	0

Chloride, Decrease to Low	0	0	1	1
Chloride, Change to Normal or No Change	8	7	5	10
Chloride, Increase to High	4	5	6	1
CO2, Decrease to Low	5	3	3	1
CO2, Change to Normal or No Change	5	7	9	8
CO2, Increase to High	1	2	0	3
Protein, Decrease to Low	3	7	7	6
Protein, Change to Normal or No Change	8	5	4	5
Protein, Increase to High	1	0	1	1
LDH, Decrease to Low	0	0	0	1
LDH, Change to Normal or No Change	4	4	3	4
LDH, Increase to High	8	8	9	7

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
DB, Decrease to Low	0	0	0	0
DB, Change to Normal or No Change	9	13	10	14
DB, Increase to High	3	5	2	2
Calcium, Decrease to Low	5	9	2	5
Calcium, Change to Normal or No Change	8	8	6	11
Calcium, Increase to High	1	2	4	1
Chloride, Decrease to Low	3	3	1	2
Chloride, Change to Normal or No Change	7	9	10	12
Chloride, Increase to High	4	6	1	2
CO2, Decrease to Low	5	4	4	2
CO2, Change to Normal or No Change	6	14	8	11
CO2, Increase to High	2	1	0	3
Protein, Decrease to Low	7	11	7	10
Protein, Change to Normal or No Change	5	5	4	5
Protein, Increase to High	1	2	1	1
LDH, Decrease to Low	1	0	2	0
LDH, Change to Normal or No Change	4	1	4	5
LDH, Increase to High	8	17	8	11

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with Worst-case change post baseline urinalysis

results: Occult Blood and Protein - All treated population

End point title	Number of participants with Worst-case change post baseline urinalysis results: Occult Blood and Protein - All treated population[11]

End point description:

Urine samples were collected to analyze presence of occult blood and protein in urine by dipstick method. Data for worst-case post baseline urinalysis results is presented. Result for urinalysis parameters were recorded as no change/decreased and increase to trace, 1+, 2+, 3+, >3+ indicating proportional concentrations in the urine sample. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Occult Blood, No Change/Decreased	5	2	6	6
Occult Blood, Increase to TRACE	1	2	3	4
Occult Blood, Increase to 1+	1	0	1	0
Occult Blood, Increase to 2+	3	0	2	2
Occult Blood, Increase to 3+	0	0	0	1
Occult Blood, Increase to >3+	0	0	1	0
Protein, No Change/Decreased	5	2	7	3
Protein, Increase to TRACE	2	0	1	6
Protein, Increase to 1+	1	0	3	0
Protein, Increase to 2+	2	0	2	3
Protein, Increase to 3+	0	2	0	1
Protein, Increase to >3+	0	0	0	0

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Occult Blood, No Change/Decreased	6	8	6	9
Occult Blood, Increase to TRACE	0	2	2	1
Occult Blood, Increase to 1+	2	0	1	1
Occult Blood, Increase to 2+	1	1	2	1
Occult Blood, Increase to 3+	0	1	1	0

Occult Blood, Increase to >3+	0	0	0	0
Protein, No Change/Decreased	2	5	5	6
Protein, Increase to TRACE	1	2	2	2
Protein, Increase to 1+	2	2	4	2
Protein, Increase to 2+	2	0	1	2
Protein, Increase to 3+	1	3	0	0
Protein, Increase to >3+	1	0	0	0

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Occult Blood, No Change/Decreased	4	11	7	12
Occult Blood, Increase to TRACE	5	1	0	0
Occult Blood, Increase to 1+	1	4	2	3
Occult Blood, Increase to 2+	1	1	2	1
Occult Blood, Increase to 3+	0	1	0	0
Occult Blood, Increase to >3+	0	0	0	0
Protein, No Change/Decreased	5	8	4	5
Protein, Increase to TRACE	1	2	0	1
Protein, Increase to 1+	2	4	2	6
Protein, Increase to 2+	2	2	2	3
Protein, Increase to 3+	2	2	3	1
Protein, Increase to >3+	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in urine Potential of Hydrogen (pH) - All treated population

End point title	Change from baseline in urine Potential of Hydrogen (pH) - All treated population[12]

End point description:

Urine samples were collected to analyze urine pH levels. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	4	13	12
Units: Potential of Hydrogen (pH)				
arithmetic mean (standard deviation)				
Baseline (Day 1)	5.9 (± 0.46)	5.8 (± 0.65)	6.0 (± 0.90)	5.8 (± 0.69)
End of Treatment	0.1 (± 1.08)	-0.2 (± 0.76)	0.4 (± 1.38)	0.2 (± 0.29)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Potential of Hydrogen (pH)				
arithmetic mean (standard deviation)				
Baseline (Day 1)	6.1 (± 0.68)	5.8 (± 0.62)	6.4 (± 0.87)	5.6 (± 0.48)
End of Treatment	-0.3 (± 0.61)	0.6 (± 0.42)	-0.5 (± 0.50)	0.2 (± 0.66)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Potential of Hydrogen (pH)				
arithmetic mean (standard deviation)				
Baseline (Day 1)	5.9 (± 0.82)	6.1 (± 0.82)	5.9 (± 1.18)	5.7 (± 0.70)
End of Treatment	0.4 (± 1.03)	0.2 (± 0.80)	0.4 (± 0.55)	0.2 (± 1.05)

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in urine specific gravity - All treated population

End point title	Change from baseline in urine specific gravity - All treated population[13]

End point description:

Urine samples were collected to analyze urine specific gravity using dipstick method. Baseline (Day 1) was defined as latest pre-dose assessment with a non-missing value, including unscheduled visits.

End point type	Primary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	4	13	11
Units: Ratio				
arithmetic mean (standard deviation)				
Baseline (Day 1)	1.0217 (± 0.00687)	1.0253 (± 0.00660)	1.0169 (± 0.00946)	1.0175 (± 0.00682)
End of Treatment	0.0003 (± 0.00058)	-0.0090 (± 0.01217)	-0.0013 (± 0.01072)	0.0023 (± 0.00643)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	12	9	11
Units: Ratio				
arithmetic mean (standard deviation)				
Baseline (Day 1)	1.0217 (± 0.00931)	1.0175 (± 0.00544)	1.0133 (± 0.00661)	1.0167 (± 0.00736)
End of Treatment	0.0075 (± 0.00354)	-0.0020 (± 0.00671)	0.0050 (± 0.00707)	0.0029 (± 0.01029)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	18	11	14
Units: Ratio				
arithmetic mean (standard deviation)				
Baseline (Day 1)	1.0193 (± 0.00612)	1.0152 (± 0.00817)	1.0174 (± 0.00713)	1.0139 (± 0.00627)
End of Treatment	-0.0010 (± 0.00529)	0.0005 (± 0.00782)	-0.0026 (± 0.00792)	0.0067 (± 0.00830)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in vital Signs: Diastolic blood pressure (DBP) and Systolic blood pressure (SBP) - All treated population

End point title	Change from Baseline in vital Signs: Diastolic blood pressure (DBP) and Systolic blood pressure (SBP) - All treated population[14]

End point description:

Blood pressures (DBP and SBP) were measured after resting for at least 5 minutes in a supine or semi-recumbent position. Baseline (Day 1) was defined as latest pre-dose assessment with a non-missing value, including unscheduled visits. Change from Baseline was calculated as post-dose visit value minus Baseline value. 99999 = Data cannot be evaluated for single participant. 88888 = Data was not collected for particular timepoint.

End point type	Primary

End point timeframe:

Baseline (Day 1, predose) and up to approximately 4.5 years

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
DBP, BASELINE (Day 1)	72.3 (± 7.67)	86.0 (± 12.49)	79.5 (± 9.36)	71.4 (± 12.04)
DBP, WEEK 79 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 79 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 79 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 91 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 94 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 109 DAY 1, Predose	5.0 (± 99999)	88888 (± 88888)	2.0 (± 99999)	-1.7 (± 2.08)
DBP, WEEK 109 DAY 1, 0.25hour Post-Dose	-4.0 (± 99999)	88888 (± 88888)	-2.0 (± 99999)	0.0 (± 6.24)
DBP, WEEK 109 DAY 1, 1hour Post-Dose	9.0 (± 99999)	88888 (± 88888)	2.0 (± 99999)	0.0 (± 5.57)
DBP, WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-2.0 (± 2.83)

DBP, WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	1.0 (± 7.07)
DBP, WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	4.5 (± 3.54)
DBP, WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	5.0 (± 99999)	88888 (± 88888)
DBP, WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	10.0 (± 99999)	88888 (± 88888)
DBP, WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	4.0 (± 99999)	88888 (± 88888)
DBP, WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, Predose	88888 (± 88888)	-14.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	-10.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	-3.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-2.0 (± 99999)
DBP, WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-10.0 (± 99999)
DBP, WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	2.0 (± 99999)
SBP, BASELINE (Day 1)	127.8 (± 18.62)	137.5 (± 7.05)	136.1 (± 26.03)	125.3 (± 15.71)
SBP, WEEK 79 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 79 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 79 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 91 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 94 DAY 1, 1hour Post-Dose	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
SBP, WEEK 109 DAY 1, Predose	9.0 (± 99999)	88888 (± 88888)	-1.0 (± 99999)	-4.7 (± 16.01)
SBP, WEEK 109 DAY 1, 0.25hour Post-Dose	3.0 (± 99999)	99999 (± 99999)	1.0 (± 99999)	1.3 (± 15.89)
SBP, WEEK 109 DAY 1, 1hour Post-Dose	3.0 (± 99999)	88888 (± 88888)	-3.0 (± 99999)	7.3 (± 16.56)
SBP, WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-9.0 (± 1.41)

SBP, WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	3.0 (± 9.90)
SBP, WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	5.0 (± 19.80)
SBP, WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	-3.0 (± 99999)	88888 (± 88888)
SBP, WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	13.0 (± 99999)	88888 (± 88888)
SBP, WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	7.0 (± 99999)	88888 (± 88888)
SBP, WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, Predose	88888 (± 88888)	-7.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	-7.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	-5.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	18.0 (± 99999)
SBP, WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	15.0 (± 99999)
SBP, WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	32.0 (± 99999)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
DBP, BASELINE (Day 1)	73.6 (± 17.15)	75.1 (± 9.08)	78.4 (± 11.13)	76.1 (± 7.14)
DBP, WEEK 79 DAY 1, Predose	-5.0 (± 99999)	3.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 79 DAY 1, 0.25hour Post-Dose	-8.0 (± 99999)	-3.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 79 DAY 1, 1hour Post-Dose	-5.0 (± 99999)	-6.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 91 DAY 1, Predose	88888 (± 88888)	6.0 (± 99999)	88888 (± 88888)	4.0 (± 99999)
DBP, WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	0.0 (± 0.0)	88888 (± 88888)	10.0 (± 99999)
DBP, WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	10.0 (± 99999)	88888 (± 88888)	3.0 (± 99999)

DBP, WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	-24.0 (± 99999)	88888 (± 88888)
DBP, WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-21.0 (± 99999)	88888 (± 88888)
DBP, WEEK 94 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-21.0 (± 99999)	88888 (± 88888)
DBP, WEEK 109 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 109 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 109 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, BASELINE (Day 1)	136.4 (± 18.99)	129.7 (± 15.13)	132.8 (± 17.88)	135.4 (± 16.68)
SBP, WEEK 79 DAY 1, Predose	11.0 (± 99999)	5.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 79 DAY 1, 0.25hour Post-Dose	10.0 (± 99999)	-3.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 79 DAY 1, 1hour Post-Dose	12.0 (± 99999)	-2.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 91 DAY 1, Predose	88888 (± 88888)	-5.0 (± 99999)	88888 (± 88888)	-2.0 (± 99999)
SBP, WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	-15.0 (± 99999)	88888 (± 88888)	17.0 (± 99999)
SBP, WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	21.0 (± 99999)	88888 (± 88888)	16.0 (± 99999)

SBP, WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	-28.0 (± 99999)	88888 (± 88888)
SBP, WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-30.0 (± 99999)	88888 (± 88888)
SBP, WEEK 94 DAY 1, 1hour Post-Dose	99999 (± 99999)	99999 (± 99999)	-35.0 (± 99999)	99999 (± 99999)
SBP, WEEK 109 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 109 DAY 1, 0.25hour Post-Dose	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
SBP, WEEK 109 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	12	16
Units: Millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
DBP, BASELINE (Day 1)	72.2 (± 8.52)	74.9 (± 8.77)	72.9 (± 11.85)	77.8 (± 10.61)

DBP, WEEK 79 DAY 1, Predose	19.0 (± 99999)	2.0 (± 99999)	-1.0 (± 99999)	-23.0 (± 99999)
DBP, WEEK 79 DAY 1, 0.25hour Post-Dose	12.0 (± 99999)	-2.0 (± 99999)	-11.0 (± 99999)	-14.0 (± 99999)
DBP, WEEK 79 DAY 1, 1hour Post-Dose	19.0 (± 99999)	5.0 (± 99999)	-10.0 (± 99999)	-44.0 (± 99999)
DBP, WEEK 91 DAY 1, Predose	-4.0 (± 99999)	-26.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 91 DAY 1, 0.25hour Post-Dose	1.0 (± 99999)	-15.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 91 DAY 1, 1hour Post-Dose	-2.0 (± 99999)	-16.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 94 DAY 1, Predose	4.0 (± 99999)	-7.0 (± 99999)	-2.0 (± 99999)	88888 (± 88888)
DBP, WEEK 94 DAY 1, 0.25hour Post-Dose	6.0 (± 99999)	4.0 (± 99999)	3.0 (± 99999)	88888 (± 88888)
DBP, WEEK 94 DAY 1, 1hour Post-Dose	14.0 (± 99999)	-5.0 (± 99999)	2.0 (± 99999)	88888 (± 88888)
DBP, WEEK 109 DAY 1, Predose	-4.5 (± 0.71)	6.0 (± 99999)	88888 (± 88888)	-14.0 (± 99999)
DBP, WEEK 109 DAY 1, 0.25hour Post-Dose	1.5 (± 7.78)	6.0 (± 99999)	88888 (± 88888)	-21.0 (± 99999)
DBP, WEEK 109 DAY 1, 1hour Post-Dose	5.5 (± 2.12)	3.0 (± 99999)	88888 (± 88888)	-27.0 (± 99999)
DBP, WEEK 133 DAY 1, Predose	6.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-16.0 (± 99999)
DBP, WEEK 133 DAY 1, 0.25hour Post-Dose	3.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-18.0 (± 99999)
DBP, WEEK 133 DAY 1, 1hour Post-Dose	8.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-14.0 (± 99999)
DBP, WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, Predose	11.0 (± 99999)	-16.5 (± 26.16)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, 0.25hour Post-Dose	6.0 (± 99999)	3.0 (± 4.24)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 1, 1hour Post-Dose	7.0 (± 99999)	-11.0 (± 16.97)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, Predose	11.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, 0.25hour Post-Dose	6.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 169 DAY 8, 1hour Post-Dose	-5.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
DBP, WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, BASELINE (Day 1)	122.3 (± 13.94)	143.3 (± 25.93)	126.8 (± 21.48)	138.5 (± 21.29)

SBP, WEEK 79 DAY 1, Predose	8.0 (± 99999)	16.0 (± 99999)	-17.0 (± 99999)	-21.0 (± 99999)
SBP, WEEK 79 DAY 1, 0.25hour Post-Dose	8.0 (± 99999)	9.0 (± 99999)	-36.0 (± 99999)	-7.0 (± 99999)
SBP, WEEK 79 DAY 1, 1hour Post-Dose	-1.0 (± 99999)	0.0 (± 0.0)	-41.0 (± 99999)	-1.0 (± 99999)
SBP, WEEK 91 DAY 1, Predose	4.0 (± 99999)	-22.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 91 DAY 1, 0.25hour Post-Dose	12.0 (± 99999)	-31.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 91 DAY 1, 1hour Post-Dose	4.0 (± 99999)	-15.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 94 DAY 1, Predose	-5.0 (± 99999)	-38.0 (± 99999)	12.0 (± 99999)	88888 (± 88888)
SBP, WEEK 94 DAY 1, 0.25hour Post-Dose	-4.0 (± 99999)	-23.0 (± 99999)	3.0 (± 99999)	88888 (± 88888)
SBP, WEEK 94 DAY 1, 1hour Post-Dose	-4.0 (± 99999)	-32.0 (± 99999)	-5.0 (± 99999)	99999 (± 99999)
SBP, WEEK 109 DAY 1, Predose	-1.0 (± 5.66)	-11.0 (± 99999)	88888 (± 88888)	-22.0 (± 99999)
SBP, WEEK 109 DAY 1, 0.25hour Post-Dose	-7.5 (± 0.71)	0.0 (± 0.0)	99999 (± 88888)	-23.0 (± 99999)
SBP, WEEK 109 DAY 1, 1hour Post-Dose	-1.5 (± 4.95)	8.0 (± 99999)	88888 (± 88888)	-31.0 (± 99999)
SBP, WEEK 133 DAY 1, Predose	4.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-16.0 (± 99999)
SBP, WEEK 133 DAY 1, 0.25hour Post-Dose	-3.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-2.0 (± 99999)
SBP, WEEK 133 DAY 1, 1hour Post-Dose	-1.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-1.0 (± 99999)
SBP, WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, Predose	-5.0 (± 99999)	-16.5 (± 28.99)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, 0.25hour Post-Dose	-5.0 (± 99999)	-9.5 (± 7.78)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 1, 1hour Post-Dose	-1.0 (± 99999)	-6.5 (± 9.19)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, Predose	10.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, 0.25hour Post-Dose	11.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 169 DAY 8, 1hour Post-Dose	17.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
SBP, WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in vital Signs : Pulse Rate - All treated population

End point title	Change from Baseline in vital Signs : Pulse Rate - All treated population[15]

End point description:

Pulse rate was measured after resting for at least 5 minutes in a supine or semi-recumbent position. Baseline (Day 1) was defined as latest pre-dose assessment with a non-missing value, including unscheduled visits. Change from Baseline was calculated as post-dose visit value minus Baseline value. 99999 = Data cannot be evaluated for single participant. 88888 = Data was not collected for particular timepoint.

End point type	Primary

End point timeframe:

Baseline (Day 1, pre-dose) and up to approximately 4.5 years

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: beats per minute				
arithmetic mean (standard deviation)				
BASELINE (Day 1)	72.8 (± 9.01)	73.8 (± 11.90)	76.0 (± 17.10)	72.8 (± 14.65)
WEEK 79 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 79 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 79 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 109 DAY 1, Predose	-19.0 (± 99999)	88888 (± 88888)	-22.0 (± 99999)	8.3 (± 5.13)

WEEK 109 DAY 1, 0.25hour Post-Dose	-18.0 (± 99999)	88888 (± 88888)	-24.0 (± 99999)	0.3 (± 3.06)
WEEK 109 DAY 1, 1hour Post-Dose	-4.0 (± 99999)	88888 (± 88888)	-25.0 (± 99999)	1.3 (± 5.69)
WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	6.5 (± 9.19)
WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	4.5 (± 0.71)
WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	5.5 (± 2.12)
WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	-8.0 (± 99999)	88888 (± 88888)
WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-10.0 (± 99999)	88888 (± 88888)
WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-9.0 (± 99999)	88888 (± 88888)
WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, Predose	88888 (± 88888)	-7.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	-5.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	-8.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-4.0 (± 99999)
WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	2.0 (± 99999)
WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	8.0 (± 99999)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: beats per minute				
arithmetic mean (standard deviation)				
BASELINE (Day 1)	73.7 (± 13.05)	76.2 (± 12.69)	75.5 (± 11.21)	79.6 (± 13.36)
WEEK 79 DAY 1, Predose	-9.0 (± 99999)	-18.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 79 DAY 1, 0.25hour Post-Dose	-6.0 (± 99999)	-6.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 79 DAY 1, 1hour Post-Dose	-18.0 (± 99999)	6.0 (± 99999)	88888 (± 88888)	88888 (± 88888)

WEEK 91 DAY 1, Predose	88888 (± 88888)	1.0 (± 99999)	88888 (± 88888)	-5.0 (± 99999)
WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	-2.0 (± 99999)	88888 (± 88888)	-19.0 (± 99999)
WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	-6.0 (± 99999)	88888 (± 88888)	-11.0 (± 99999)
WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	-5.0 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-4.0 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-4.0 (± 99999)	88888 (± 88888)
WEEK 109 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 109 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 109 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	12	16
Units: beats per minute				
arithmetic mean (standard deviation)				
BASELINE (Day 1)	73.3 (± 14.31)	74.1 (± 10.76)	81.0 (± 10.05)	75.3 (± 10.82)
WEEK 79 DAY 1, Predose	-14.0 (± 99999)	9.0 (± 99999)	1.0 (± 99999)	4.0 (± 99999)
WEEK 79 DAY 1, 0.25hour Post-Dose	6.0 (± 99999)	-2.0 (± 99999)	2.0 (± 99999)	-9.0 (± 99999)
WEEK 79 DAY 1, 1hour Post-Dose	13.0 (± 99999)	-2.0 (± 99999)	4.0 (± 99999)	-6.0 (± 99999)
WEEK 91 DAY 1, Predose	24.0 (± 99999)	-5.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 0.25hour Post-Dose	12.0 (± 99999)	-9.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 1hour Post-Dose	11.0 (± 99999)	-19.0 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, Predose	-14.0 (± 99999)	21.0 (± 99999)	13.0 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 0.25hour Post-Dose	-22.0 (± 99999)	16.0 (± 99999)	12.0 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 1hour Post-Dose	-28.0 (± 99999)	11.0 (± 99999)	14.0 (± 99999)	88888 (± 88888)
WEEK 109 DAY 1, Predose	-6.0 (± 8.49)	-12.0 (± 99999)	88888 (± 88888)	-9.0 (± 99999)
WEEK 109 DAY 1, 0.25hour Post-Dose	10.5 (± 41.72)	-16.0 (± 99999)	88888 (± 88888)	-8.0 (± 99999)
WEEK 109 DAY 1, 1hour Post-Dose	-8.0 (± 11.31)	-12.0 (± 99999)	88888 (± 88888)	0.0 (± 0.0)
WEEK 133 DAY 1, Predose	-11.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-5.0 (± 99999)
WEEK 133 DAY 1, 0.25hour Post-Dose	-12.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-5.0 (± 99999)
WEEK 133 DAY 1, 1hour Post-Dose	-16.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	-17.0 (± 99999)
WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, Predose	-15.0 (± 99999)	-21.0 (± 5.66)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 0.25hour Post-Dose	-23.0 (± 99999)	-19.0 (± 2.83)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 1hour Post-Dose	-20.0 (± 99999)	-21.0 (± 1.41)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, Predose	-21.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 0.25hour Post-Dose	-17.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 1hour Post-Dose	-20.0 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in vital Signs : Temperature - All treated population

End point title	Change from Baseline in vital Signs : Temperature - All treated population[16]

End point description:

Temperature was measured after resting for at least 5 minutes in a supine or semi-recumbent position. Baseline (Day 1) was defined as latest pre-dose assessment with a non-missing value, including unscheduled visits. Change from Baseline was calculated as post-dose visit value minus Baseline value. 99999 = Data cannot be evaluated for single participant. 88888 = Data was not collected for particular timepoint.

End point type	Primary

End point timeframe:

Baseline (Day 1, pre-dose) and up to approximately 4.5 years

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Degree Celsius (C)				
arithmetic mean (standard deviation)				
BASELINE (Day 1)	36.61 (± 0.417)	36.70 (± 0.346)	36.46 (± 0.307)	36.43 (± 0.334)
WEEK 79 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 79 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 79 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

WEEK 109 DAY 1, Predose	-0.90 (± 99999)	88888 (± 88888)	-0.80 (± 99999)	0.20 (± 0.173)
WEEK 109 DAY 1, 0.25hour Post-Dose	-1.20 (± 99999)	88888 (± 88888)	-0.80 (± 99999)	0.07 (± 0.153)
WEEK 109 DAY 1, 1hour Post-Dose	-1.20 (± 99999)	88888 (± 88888)	-0.50 (± 99999)	0.10 (± 0.173)
WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	0.60 (± 0.283)
WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	0.25 (± 0.071)
WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	0.45 (± 0.071)
WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	0.20 (± 99999)	88888 (± 88888)
WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-0.10 (± 99999)	88888 (± 88888)
WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	0.00 (± 0.00)	88888 (± 88888)
WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, Predose	88888 (± 88888)	-0.30 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	-0.40 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	-0.40 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-0.10 (± 99999)
WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-0.10 (± 99999)
WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	-0.20 (± 99999)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Degree Celsius (C)				
arithmetic mean (standard deviation)				
BASELINE (Day 1)	36.46 (± 0.348)	36.44 (± 0.291)	36.52 (± 0.432)	36.68 (± 0.305)
WEEK 79 DAY 1, Predose	-0.30 (± 99999)	0.10 (± 99999)	88888 (± 88888)	88888 (± 88888)

WEEK 79 DAY 1, 0.25hour Post-Dose	-0.30 (± 99999)	0.10 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 79 DAY 1, 1hour Post-Dose	-0.10 (± 99999)	0.40 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, Predose	88888 (± 88888)	0.40 (± 99999)	88888 (± 88888)	-0.60 (± 99999)
WEEK 91 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	0.40 (± 99999)	88888 (± 88888)	-0.80 (± 99999)
WEEK 91 DAY 1, 1hour Post-Dose	88888 (± 88888)	0.50 (± 99999)	88888 (± 88888)	-0.50 (± 99999)
WEEK 94 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	-0.20 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-0.30 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	-0.40 (± 99999)	88888 (± 88888)
WEEK 109 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 109 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 109 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 133 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 133 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 133 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	12	16
Units: Degree Celsius (C)				
arithmetic mean (standard deviation)				
BASELINE (Day 1)	36.53 (± 0.338)	36.48 (± 0.571)	36.51 (± 0.581)	36.58 (± 0.397)
WEEK 79 DAY 1, Predose	0.70 (± 99999)	-0.10 (± 99999)	1.30 (± 99999)	0.00 (± 0.00)
WEEK 79 DAY 1, 0.25hour Post-Dose	-0.20 (± 99999)	-0.10 (± 99999)	1.60 (± 99999)	0.00 (± 0.00)
WEEK 79 DAY 1, 1hour Post-Dose	0.50 (± 99999)	0.00 (± 0.00)	1.40 (± 99999)	0.00 (± 0.00)
WEEK 91 DAY 1, Predose	0.50 (± 99999)	-0.70 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 0.25hour Post-Dose	0.10 (± 99999)	0.20 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 91 DAY 1, 1hour Post-Dose	0.50 (± 99999)	0.30 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 94 DAY 1, Predose	0.10 (± 99999)	-0.30 (± 99999)	0.30 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 0.25hour Post-Dose	0.30 (± 99999)	0.10 (± 99999)	0.30 (± 99999)	88888 (± 88888)
WEEK 94 DAY 1, 1hour Post-Dose	0.00 (± 0.00)	0.10 (± 99999)	0.30 (± 99999)	88888 (± 88888)
WEEK 109 DAY 1, Predose	0.20 (± 0.283)	-0.20 (± 99999)	88888 (± 88888)	0.40 (± 99999)
WEEK 109 DAY 1, 0.25hour Post-Dose	0.15 (± 0.071)	0.20 (± 99999)	88888 (± 88888)	0.40 (± 99999)
WEEK 109 DAY 1, 1hour Post-Dose	0.15 (± 0.071)	0.10 (± 99999)	88888 (± 88888)	0.40 (± 99999)
WEEK 133 DAY 1, Predose	0.40 (± 99999)	88888 (± 88888)	88888 (± 88888)	1.00 (± 99999)
WEEK 133 DAY 1, 0.25hour Post-Dose	0.30 (± 99999)	88888 (± 88888)	88888 (± 88888)	0.70 (± 99999)
WEEK 133 DAY 1, 1hour Post-Dose	0.10 (± 99999)	88888 (± 88888)	88888 (± 88888)	0.20 (± 99999)
WEEK 153 DAY 8, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 153 DAY 8, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, Predose	-0.20 (± 99999)	0.10 (± 99999)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 0.25hour Post-Dose	0.10 (± 99999)	0.05 (± 0.636)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 1, 1hour Post-Dose	0.10 (± 99999)	-0.05 (± 0.071)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, Predose	-0.20 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 0.25hour Post-Dose	0.40 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 169 DAY 8, 1hour Post-Dose	-0.30 (± 99999)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 173 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

WEEK 173 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, Predose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, 0.25hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)
WEEK 221 DAY 1, 1hour Post-Dose	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Primary: Overall Response Rate (ORR) as defined by the International Myeloma Working Group (IMWG) Uniform Response Criteria for Multiple Myeloma (MM) - All treated population

End point title	Overall Response Rate (ORR) as defined by the International Myeloma Working Group (IMWG) Uniform Response Criteria for Multiple Myeloma (MM) - All treated population[17]

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. Confidence intervals were based on the exact method.

End point type	Primary

End point timeframe:

Up to approximately 4.5 years

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Percentage of Participants				
number (confidence interval 95%)	58 (27.7 to 84.8)	75 (19.4 to 99.4)	69 (38.6 to 90.9)	69 (41.3 to 89.0)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex

			Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of Participants				
number (confidence interval 95%)	50 (21.1 to 78.9)	83 (51.6 to 97.9)	92 (61.5 to 99.8)	75 (42.8 to 94.5)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Percentage of Participants				
number (confidence interval 95%)	62 (31.6 to 86.1)	78 (52.4 to 93.6)	50 (21.1 to 78.9)	69 (41.3 to 89.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum observed concentration (Cmax) for belantamab mafodotin antibody-drug conjugate (ADC), Treatment A - Pharmacokinetic (PK) population

End point title	Maximum observed concentration (Cmax) for belantamab mafodotin antibody-drug conjugate (ADC), Treatment A - Pharmacokinetic (PK) population[18]

End point description:

Blood samples were collected at indicated timepoints for pharmacokinetic (PK) analysis. PK parameter was determined using standard non-compartmental methods. Pharmacokinetic (PK) population included all participants in all treated population from whom at least one PK sample was obtained, analyzed, and was measurable. 88888 = Data was not collected for particular timepoint.

End point type	Secondary

End point timeframe:

Cycle 1: Pre-Dose, 0, 2 and 24 hours post-dose on Days 1 and 8

Notes:

[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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Microgram/ millilitre (ug/mL)				
geometric mean (geometric coefficient of variation)				

CYCLE 1 DAY 1	43.58 (± 21.78)	36.41 (± 17.06)	25.22 (± 16.53)	39.99 (± 25.03)
CYCLE 1 DAY 8	88888 (± 88888)	88888 (± 88888)	27.60 (± 16.27)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-672h) for belantamab mafodotin ADC, Treatment A - PK population

End point title	AUC (0-672h) for belantamab mafodotin ADC, Treatment A - PK population[19]

End point description:

Blood samples were collected at indicated timepoints for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post-Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 11; Cycle 1 Day 15-21; Cycle 1 Day 28

Notes:

[19] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	9	9
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	4093.12 (± 24.45)	5114.28 (± 34.72)	4699.00 (± 11.10)	4432.11 (± 17.65)

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration time curve (AUC) from time 0 to 504 hours (0-504h) for belantamab mafodotin ADC, Treatment A - PK population

End point title	Area under the concentration time curve (AUC) from time 0 to 504 hours (0-504h) for belantamab mafodotin ADC, Treatment A - PK population[20]

End point description:

Blood samples were collected at indicated timepoints for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post-Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 11; Cycle 1 Day 15-21

Notes:

[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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	9	9
Units: Hour*microgram/millilitre (h*ug/mL)				
geometric mean (geometric coefficient of variation)	3848.41 (± 24.25)	4802.83 (± 34.51)	4365.82 (± 10.25)	4127.66 (± 17.98)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to reach maximum observed concentration (Tmax) for belantamab mafodotin ADC, Treatment A - PK population

End point title	Time to reach maximum observed concentration (Tmax) for belantamab mafodotin ADC, Treatment A - PK population[21]

End point description:

Blood samples were collected at indicated timepoints for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected for particular timepoint.

End point type	Secondary

End point timeframe:

Cycle 1: Pre-Dose, 0, 2 and 24 Hours Post-Dose on Days 1 and 8

Notes:

[21] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	15
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	2.050 (0.57 to 2.37)	1.342 (0.50 to 2.17)	1.100 (0.57 to 2.20)	2.000 (0.53 to 2.42)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	1.108 (0.57 to 23.93)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Time of last observed quantifiable concentration (tlast) for belantamab mafodotin ADC, Treatment A - PK population

End point title	Time of last observed quantifiable concentration (tlast) for belantamab mafodotin ADC, Treatment A - PK population[22]

End point description:

Blood samples were collected at indicated timepoints for PK analysis. PK parameter was determined using standard non-compartmental methods. Tlast is the time of last observed quantifiable concentration of belantamab mafodotin in Cycle 1 which extended beyond protocol defined duration for some participants across treatment groups.

End point type	Secondary

End point timeframe:

Pre-Dose Cycle 1 Day 1 to pre-dose Cycle 2 Day 28

Notes:

[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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Hour				
median (full range (min-max))	181.467 (25.50 to 698.22)	685.608 (191.58 to 697.75)	674.833 (94.40 to 1273.75)	671.717 (2.00 to 1342.83)

Statistical analyses

No statistical analyses for this end point

Secondary: Trough concentration prior to the next dose for each cycle (Ctrough) for belantamab mafodotin ADC, Treatment A - PK population

End point title	Trough concentration prior to the next dose for each cycle (Ctrough) for belantamab mafodotin ADC, Treatment A - PK population[23]

End point description:

Blood samples were collected at indicated timepoints for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported

if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Cycle 1: Pre-Dose, 0, 2 and 24 Hours Post-Dose on Days 1 and 8; Weeks 5, 9, and 13: Pre-Dose and Post-Dose on Days 1 and 8

Notes:

[23] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	88888 (88888 to 88888)	1.79 (0.7 to 1.8)	3.52 (2.5 to 4.7)	1.08 (0.7 to 1.5)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	1.30 (0.7 to 2.4)	88888 (88888 to 88888)
WEEK 5 DAY 1	88888 (88888 to 88888)	77777 (77777 to 77777)	5.05 (2.4 to 7.0)	77777 (77777 to 77777)
WEEK 5 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	1.17 (0.1 to 3.6)	88888 (88888 to 88888)
WEEK 9 DAY 1	88888 (88888 to 88888)	77777 (77777 to 77777)	4.89 (3.0 to 8.4)	77777 (77777 to 77777)
WEEK 9 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	2.03 (1.8 to 3.9)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Observed plasma concentration at the end of infusion (C-EOI) for belantamab mafodotin ADC, Treatment A - PK population

End point title	Observed plasma concentration at the end of infusion (C-EOI) for belantamab mafodotin ADC, Treatment A - PK population[24]

End point description:

Blood samples were collected at indicated timepoints for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Cycle 1: Pre-Dose, 0, 2 and 24 Hours Post-Dose on Days 1 and Day 8; Weeks 5, 9, and 13: Pre-Dose and Post-Dose on Days 1 and 8

Notes:

[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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4	12	15
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	39.10 (27.2 to 49.5)	36.05 (29.6 to 44.5)	25.05 (18.2 to 31.5)	41.80 (14.0 to 51.3)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	26.55 (18.6 to 35.2)	88888 (88888 to 88888)
WEEK 5 DAY 1	88888 (88888 to 88888)	35.45 (33.8 to 42.0)	23.00 (20.5 to 27.2)	36.75 (25.6 to 96.2)
WEEK 5 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	27.10 (23.6 to 41.8)	88888 (88888 to 88888)
WEEK 9 DAY 1	42.35 (31.1 to 49.5)	77777 (77777 to 77777)	23.50 (15.3 to 31.8)	77777 (77777 to 77777)
WEEK 9 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	25.60 (17.1 to 31.1)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	38.40 (28.1 to 50.9)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for belantamab mafodotin ADC. Treatment B - PK population

End point title	Cmax for belantamab mafodotin ADC. Treatment B - PK population[25]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	52.24 (± 31.87)	49.50 (± 21.38)	61.16 (± 36.74)	51.29 (± 26.03)
CYCLE 1 DAY 8	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	21.34 (± 34.67)	46.95 (± 23.24)	27.79 (± 37.28)	64.00 (± 38.60)
CYCLE 1 DAY 8	24.46 (± 32.10)	88888 (± 88888)	31.96 (± 32.79)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-504h) for belantamab mafodotin ADC, Treatment B - PK population

End point title	AUC (0-504h) for belantamab mafodotin ADC, Treatment B - PK population[26]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 11; Cycle 1 Day 21

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	10	4	7
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	6129.71 (± 23.83)	4451.74 (± 23.33)	6073.99 (± 37.06)	5395.98 (± 20.49)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	15	8	11
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	4341.73 (± 22.36)	5013.84 (± 31.91)	5702.03 (± 26.30)	6230.16 (± 35.02)

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for belantamab mafodotin ADC, Treatment B - PK population

End point title	Tmax for belantamab mafodotin ADC, Treatment B - PK population[27]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Hour				
median (full range (min-max))				

CYCLE 1 DAY 1	1.900 (0.63 to 22.50)	1.125 (0.55 to 2.62)	2.025 (0.63 to 25.95)	1.175 (0.62 to 2.57)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	1.233 (0.50 to 2.22)	1.308 (0.45 to 2.70)	0.583 (0.50 to 2.20)	2.000 (0.52 to 3.83)
CYCLE 1 DAY 8	0.733 (0.52 to 336.75)	88888 (88888 to 88888)	0.642 (0.40 to 2.05)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-1008h) for belantamab mafodotin ADC, Treatment B - PK population

End point title	AUC (0-1008h) for belantamab mafodotin ADC, Treatment B - PK population[28]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. AUC was derived only for STRETCH and S/D STRETCH cohorts.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 11; Cycle 1 Day 22; Pre Pre-Dose and Post-Dose on Week 5 Day 7

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	10	6	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	7084.63 (± 24.82)	7396.49 (± 25.94)	6487.41 (± 26.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for belantamab mafodotin ADC, Treatment B - PK population

End point title	tlast for belantamab mafodotin ADC, Treatment B - PK population[29]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. Tlast is the time of last observed quantifiable concentration of belantamab mafodotin in Cycle 1 which extended beyond protocol defined duration for some participants across treatment groups.

End point type	Secondary

End point timeframe:

Pre-Dose Cycle 1 Day 1 to pre-dose Cycle 5 Day 1

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Hour				
median (full range (min-max))	540.250 (75.67 to 1052.33)	505.592 (503.75 to 1220.95)	1009.933 (500.93 to 1489.00)	755.442 (22.68 to 2018.57)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Hour				
median (full range (min-max))	504.567 (144.83 to 1351.17)	506.817 (167.50 to 577.33)	503.458 (239.72 to 1584.50)	506.092 (2.00 to 2022.58)

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough for belantamab mafodotin ADC, Treatment B - PK population

End point title	Ctrough for belantamab mafodotin ADC, Treatment B - PK population[30]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 4 Day 1, Week 7 Day 1, Week 10 Day 1, Week 13 Day 1, Week 13 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	1.12 (0.5 to 1.5)	1.92 (0.6 to 3.9)	0.63 (0.5 to 1.2)	0.84 (0.5 to 1.0)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 4 DAY 1	88888 (88888 to 88888)	3.23 (1.4 to 5.4)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 1	77777 (77777 to 77777)	3.90 (0.5 to 6.4)	1.24 (0.6 to 2.8)	77777 (77777 to 77777)
WEEK 10 DAY 1	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	1.40 (0.7 to 2.1)	77777 (77777 to 77777)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: ug/mL				
median (full range (min-max))				

CYCLE 1 DAY 1	3.50 (1.8 to 7.1)	2.12 (1.1 to 5.4)	4.25 (1.6 to 11.7)	2.10 (0.5 to 4.3)
CYCLE 1 DAY 8	3.72 (0.7 to 24.3)	88888 (88888 to 88888)	3.93 (1.7 to 9.0)	88888 (88888 to 88888)
WEEK 4 DAY 1	4.39 (3.0 to 8.6)	1.32 (0.6 to 8.6)	3.62 (1.4 to 6.2)	2.53 (0.6 to 4.3)
WEEK 7 DAY 1	5.85 (4.0 to 8.1)	2.72 (0.1 to 3.7)	10.10 (5.7 to 13.9)	88888 (88888 to 88888)
WEEK 10 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)
WEEK 13 DAY 1	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)	77777 (77777 to 77777)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: C-EOI for belantamab mafodotin ADC, Treatment B - PK population

End point title	C-EOI for belantamab mafodotin ADC, Treatment B - PK population[31]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 4 Day 1, Week 7 Day 1, Week 10 Day 1, Week 13 Day 1, Week 13 Day 8; Week 7 Day 8, Week 7 Day 11, Week 10 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	44.75 (26.8 to 68.0)	44.05 (36.1 to 61.5)	52.00 (22.8 to 88.8)	45.25 (31.4 to 76.7)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 4 DAY 1	88888 (88888 to 88888)	46.00 (30.5 to 64.0)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 1	48.60 (37.9 to 83.6)	44.30 (3.4 to 71.8)	36.45 (26.5 to 76.9)	42.50 (25.9 to 84.1)

WEEK 7 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 11	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 10 DAY 1	88888 (88888 to 88888)	88888 (88888 to 88888)	38.00 (31.9 to 43.3)	77777 (77777 to 77777)
WEEK 10 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	77777 (77777 to 77777)	43.30 (31.1 to 60.1)	77777 (77777 to 77777)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	22.30 (12.9 to 30.6)	45.80 (29.1 to 57.6)	30.10 (11.0 to 49.1)	54.85 (37.2 to 215.0)
CYCLE 1 DAY 8	22.60 (12.2 to 48.4)	88888 (88888 to 88888)	32.60 (17.5 to 55.7)	88888 (88888 to 88888)
WEEK 4 DAY 1	27.10 (16.7 to 32.4)	44.50 (26.8 to 254.0)	26.20 (14.6 to 53.2)	51.20 (45.7 to 57.8)
WEEK 7 DAY 1	26.30 (19.1 to 29.7)	31.70 (18.2 to 62.7)	27.40 (12.1 to 38.6)	38.35 (37.0 to 55.8)
WEEK 7 DAY 8	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)
WEEK 7 DAY 11	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)
WEEK 10 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)
WEEK 10 DAY 8	77777 (77777 to 77777)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 13 DAY 1	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)	46.60 (41.4 to 62.3)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	Cmax for belantamab mafodotin (Total Antibody), Treatment A - PK population[32]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	43.09 (± 22.26)	40.18 (± 13.23)	26.64 (± 14.97)	46.95 (± 30.63)
CYCLE 1 DAY 8	88888 (± 88888)	88888 (± 88888)	35.11 (± 13.68)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-1008h) for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	AUC (0-1008h) for belantamab mafodotin (Total Antibody), Treatment A - PK population[33]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. AUC(0-1008) was derived only for Belantamab mafodotin 1.9mg/kg + Len/Dex STRETCH cohort.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post-Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 29; Pre-Dose and Post-Dose on Week 5 Day 7

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: h*ug/mL				
geometric mean (geometric coefficient	8143.85 (±			

of variation)	30.12)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-672h) for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	AUC (0-672h) for belantamab mafodotin (Total Antibody), Treatment A - PK population[34]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post-Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 11; Cycle 1 Day 15-21; Cycle 1 Day 28

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	10	9
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	7408.65 (± 36.03)	7249.58 (± 39.00)	7828.12 (± 27.15)	8146.00 (± 28.29)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-504h) for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	AUC (0-504h) for belantamab mafodotin (Total Antibody), Treatment A - PK population[35]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post-Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day

11; Cycle 1 Day 15-21

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	10	9
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	6648.19 (± 35.67)	6607.45 (± 35.62)	6909.91 (± 24.70)	7277.25 (± 28.00)

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	tlast for belantamab mafodotin (Total Antibody), Treatment A - PK population[36]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. Tlast is the time of last observed quantifiable concentration of belantamab mafodotin in Cycle 1 which extended beyond protocol defined duration for some participants across treatment groups.

End point type	Secondary

End point timeframe:

Pre-Dose Cycle 1 Day 1 to pre-dose Cycle 3 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Hour				
median (full range (min-max))	657.267 (25.50 to 1439.63)	685.875 (673.92 to 697.75)	674.833 (670.60 to 1416.93)	673.625 (2.00 to 1534.15)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-1344h) for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	AUC(0-1344h) for belantamab mafodotin (Total Antibody), Treatment A - PK population[37]

End point description:

Blood samples were collected for PK analysis. PK parameter was determinedusing standard non-compartmental methods. AUC(0-1344) was derived only for Belantamab mafodotin 1.9mg/kg + Len/Dex STRETCH cohort.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post-Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 29; Pre-Dose and Post-Dose on Week 7 Day 7

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	8633.05 (± 30.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	Tmax for belantamab mafodotin (Total Antibody), Treatment A - PK population[38]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	1.267 (0.57 to 2.37)	1.342 (0.50 to 2.17)	1.033 (0.57 to 2.20)	2.000 (0.53 to 2.82)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	1.583 (0.57 to 2.10)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	Ctrough for belantamab mafodotin (Total Antibody), Treatment A - PK population[39]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 5 Day 1, Week 5 Day 8, Week 9 Day 1, Week 9 Day 8, Week 13 Day 1, Week 13 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	12	12
Units: ug/mL				
median (full range (min-max))				

CYCLE 1 DAY 1	0.81 (0.6 to 2.0)	3.39 (0.7 to 6.1)	7.74 (1.9 to 9.9)	3.16 (1.6 to 5.9)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	3.99 (0.9 to 12.3)	88888 (88888 to 88888)
WEEK 5 DAY 1	88888 (88888 to 88888)	2.76 (1.1 to 8.1)	12.40 (7.7 to 22.6)	1.82 (0.8 to 4.5)
WEEK 5 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	6.16 (2.5 to 22.6)	88888 (88888 to 88888)
WEEK 9 DAY 1	77777 (77777 to 77777)	77777 (77777 to 77777)	15.25 (11.2 to 29.7)	77777 (77777 to 77777)
WEEK 9 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	10.50 (1.3 to 10.5)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	10.70 (0.9 to 17.0)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: C-EOI for belantamab mafodotin (Total Antibody), Treatment A - PK population

End point title	C-EOI for belantamab mafodotin (Total Antibody), Treatment A - PK population[40]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 5 Day 1, Week 5 Day 8, Week 9 Day 1, Week 9 Day 8, Week 13 Day 1, Week 13 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	4	13	16
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	42.70 (35.0 to 64.0)	36.90 (35.3 to 47.9)	27.25 (20.1 to 32.7)	47.00 (17.2 to 64.2)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	35.00 (27.8 to 40.3)	88888 (88888 to 88888)
WEEK 5 DAY 1	88888 (88888 to 88888)	42.15 (32.4 to 48.1)	27.00 (24.7 to 36.4)	45.70 (30.0 to 79.9)
WEEK 5 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	36.40 (27.8 to 50.6)	88888 (88888 to 88888)

WEEK 9 DAY 1	41.80 (33.1 to 52.9)	77777 (77777 to 77777)	31.25 (22.9 to 46.6)	77777 (77777 to 77777)
WEEK 9 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	39.20 (27.4 to 56.8)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	50.10 (39.5 to 73.3)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for belantamab mafodotin (Total Antibody) Treatment B - PK population

End point title	Cmax for belantamab mafodotin (Total Antibody) Treatment B - PK population[41]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	12	12
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	41.28 (± 16.86)	37.47 (± 12.02)	53.29 (± 23.50)	53.85 (± 12.54)
CYCLE 1 DAY 8	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	11	16
Units: ug/mL				

geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	22.92 (± 35.83)	50.32 (± 30.03)	31.06 (± 20.02)	78.29 (± 36.16)
CYCLE 1 DAY 8	29.47 (± 40.48)	88888 (± 88888)	45.31 (± 39.57)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-504h) for belantamab mafodotin (Total Antibody), Treatment B - PK population

End point title	AUC (0-504h) for belantamab mafodotin (Total Antibody), Treatment B - PK population[42]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 11; Cycle 1 Day 21

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	4	6
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	7310.17 (± 37.27)	6094.55 (± 33.37)	8386.87 (± 25.44)	9891.43 (± 29.93)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	12	7	11
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	8283.76 (± 32.51)	8207.69 (± 41.72)	9812.19 (± 27.13)	12581.08 (± 28.13)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-1008h) for belantamab mafodotin (Total Antibody), Treatment B - PK population

End point title	AUC (0-1008h) for belantamab mafodotin (Total Antibody), Treatment B - PK population[43]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. AUC(0-1008) was derived only for Belantamab mafodotin 1.9 mg/kg+ Bor/Dax STRETCH, Belantamab mafodotin 2.5 mg/kg+ Bor/Dax StepDown STRETCH and STRETCH cohorts.

End point type	Secondary

End point timeframe:

Pre-Dose, 0, 2 and 24 Hours Post Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 11; Cycle 1 Day 22; Pre-Dose and Post-Dose on Week 5 Day 7

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	11	10	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	11656.56 (± 25.11)	11328.37 (± 40.25)	11178.97 (± 49.10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for belantamab mafodotin (Total Antibody), Treatment B - PK population

End point title	Tmax for belantamab mafodotin (Total Antibody), Treatment B - PK population[44]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	12	12
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	1.900 (0.75 to 2.03)	2.033 (0.70 to 2.23)	0.983 (0.57 to 2.13)	1.142 (0.62 to 2.58)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	11	16
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	2.000 (0.50 to 2.17)	1.983 (0.45 to 2.23)	0.650 (0.50 to 2.13)	2.000 (0.52 to 2.50)
CYCLE 1 DAY 8	0.700 (0.52 to 2.50)	88888 (88888 to 88888)	0.617 (0.40 to 2.05)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for belantamab mafodotin (Total Antibody), Treatment B - PK population

End point title	tlast for belantamab mafodotin (Total Antibody), Treatment B - PK population[45]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. Tlast is the time of last observed quantifiable concentration of belantamab mafodotin in Cycle 1 which extended beyond protocol defined duration for some participants across treatment groups.

End point type	Secondary

End point timeframe:

Pre-Dose Cycle 1 Day 1 to pre-dose Cycle 9 Day 1

Notes:

[45] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Hour				
median (full range (min-max))	585.958 (75.67 to 2855.48)	504.983 (239.92 to 2155.95)	1414.500 (505.25 to 3694.62)	1031.467 (1006.72 to 4054.38)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Hour				
median (full range (min-max))	504.583 (144.83 to 1351.17)	505.483 (167.50 to 671.65)	502.883 (239.72 to 717.68)	506.808 (2.00 to 2832.25)

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough for belantamab mafodotin (Total Antibody), Treatment B - PK population

End point title	Ctrough for belantamab mafodotin (Total Antibody), Treatment B - PK population[46]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 4 Day 1, Week 7 Day 1, Week 7 Day 8, Week 10 Day 1, Week 13 Day 1, Week 13 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	10	9	11
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	3.13 (1.0 to 5.6)	5.27 (2.1 to 10.7)	1.53 (1.1 to 4.5)	1.32 (0.6 to 8.6)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 4 DAY 1	88888 (88888 to 88888)	7.97 (0.6 to 18.8)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 1	77777 (77777 to 77777)	7.66 (2.6 to 22.2)	1.72 (1.4 to 6.5)	2.32 (1.9 to 5.8)
WEEK 7 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 10 DAY 1	88888 (88888 to 88888)	88888 (88888 to 88888)	3.07 (1.4 to 3.4)	77777 (77777 to 77777)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	5.26 (1.3 to 10.5)	77777 (77777 to 77777)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	12	15
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	5.88 (1.2 to 13.5)	7.22 (1.7 to 17.2)	9.59 (3.5 to 38.9)	6.82 (1.4 to 17.4)
CYCLE 1 DAY 8	12.30 (2.7 to 33.2)	88888 (88888 to 88888)	12.05 (7.8 to 22.6)	88888 (88888 to 88888)
WEEK 4 DAY 1	14.95 (1.2 to 27.7)	3.62 (0.6 to 22.8)	11.20 (5.3 to 25.1)	5.27 (1.9 to 13.2)
WEEK 7 DAY 1	19.40 (10.3 to 34.0)	1.35 (1.1 to 21.7)	26.00 (19.1 to 31.0)	88888 (88888 to 88888)
WEEK 7 DAY 8	77777 (77777 to 77777)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 10 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)
WEEK 13 DAY 1	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)	77777 (77777 to 77777)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: C-EOI for belantamab mafodotin (Total Antibody), Treatment B - PK population

End point title	C-EOI for belantamab mafodotin (Total Antibody), Treatment B - PK population[47]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 4 Day 1, Week 7 Day 1, Week 7 Day 8, Week 7 Day 11, Week 10 Day 1, Week 13 Day 1, Week 13 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	12	12
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	36.60 (30.7 to 52.0)	36.75 (27.6 to 44.0)	52.55 (38.2 to 90.3)	51.65 (43.7 to 66.1)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 4 DAY 1	88888 (88888 to 88888)	39.20 (24.6 to 54.6)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 1	36.50 (31.8 to 67.8)	43.00 (14.3 to 78.6)	37.30 (23.3 to 65.1)	47.50 (33.3 to 67.7)
WEEK 7 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 11	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 10 DAY 1	88888 (88888 to 88888)	88888 (88888 to 88888)	42.70 (41.0 to 53.6)	77777 (77777 to 77777)
WEEK 10 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	77777 (77777 to 77777)	33.30 (27.8 to 41.6)	77777 (77777 to 77777)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	16	11	15
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	23.90 (13.9 to 33.1)	44.35 (30.3 to 63.0)	33.40 (21.2 to 40.1)	68.80 (42.5 to 241.0)
CYCLE 1 DAY 8	24.95 (16.1 to 38.2)	88888 (88888 to 88888)	42.50 (25.7 to 98.9)	88888 (88888 to 88888)
WEEK 4 DAY 1	37.00 (19.8 to 46.0)	59.50 (30.1 to 233.0)	39.40 (19.6 to 70.8)	67.85 (50.0 to 85.5)
WEEK 7 DAY 1	42.00 (24.0 to 49.5)	50.75 (29.6 to 73.8)	33.90 (20.2 to 63.0)	63.95 (44.5 to 67.6)
WEEK 7 DAY 8	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)
WEEK 7 DAY 11	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)
WEEK 10 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)
WEEK 10 DAY 8	77777 (77777 to 77777)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 13 DAY 1	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)	54.50 (52.9 to 85.3)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for belantamab mafodotin Cysteine Maleimidocaproyl Monomethyl Auristatin F (Cys-mcMMAF), Treatment A - PK population

End point title	Cmax for belantamab mafodotin Cysteine Maleimidocaproyl Monomethyl Auristatin F (Cys-mcMMAF), Treatment A - PK population[48]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4	12	13
Units: ug/mL				
geometric mean (geometric coefficient				

of variation)				
CYCLE 1 DAY 1	1.11 (± 70.59)	0.55 (± 53.90)	0.53 (± 48.23)	1.18 (± 53.35)
CYCLE 1 DAY 8	88888 (± 88888)	88888 (± 88888)	0.63 (± 28.28)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-168h) for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population

End point title	AUC (0-168h) for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population[49]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 2, and 24 Hours Post Dose on Cycle 1 Day 1, Cycle 1 Day 4 and Cycle 1 Day 7

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	11	10
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	106.21 (± 55.99)	88888 (± 88888)	43.15 (± 26.42)	113.58 (± 49.61)
CYCLE 1 DAY 8	88888 (± 88888)	88888 (± 88888)	51.31 (± 30.45)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population

End point title	Tmax for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population[50]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4	12	13
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	24.217 (1.42 to 28.58)	24.900 (23.67 to 73.42)	23.667 (1.00 to 25.42)	24.367 (2.23 to 25.92)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	23.425 (0.57 to 25.93)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-336h) for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population

End point title	AUC (0-336h) for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population[51]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. AUC (0-336h) was derived only for the Belantamab mafodotin 2.5mg/kg + Len/Dex SPLIT cohort.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 2, and 24 Hours Post Dose on Cycle 1 Day 1; Cycle 1 Day 4; Cycle 1 Day 8; Cycle 1 Day 11; Cycle 1 Day 14

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 2.5mg/kg SPLIT +			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	93.84 (± 29.16)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-EOI for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population

End point title	C-EOI for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population[52]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 5 Day 1, Week 7 Day 8, Week 9 Day 1, Week 9 Day 8, Week 13 Day 1, Week 13 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4	13	14
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	0.43 (0.3 to 1.6)	0.187 (0.160 to 0.290)	0.19 (0.1 to 1.3)	0.29 (0.1 to 1.3)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	0.29 (0.2 to 0.9)	88888 (88888 to 88888)
WEEK 5 DAY 1	88888 (88888 to 88888)	0.16 (0.1 to 0.4)	0.13 (0.1 to 0.3)	0.28 (0.2 to 1.0)
WEEK 5 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	0.23 (0.2 to 0.4)	88888 (88888 to 88888)
WEEK 9 DAY 1	0.29 (0.2 to 0.5)	77777 (77777 to 77777)	0.13 (0.1 to 0.7)	77777 (77777 to 77777)
WEEK 9 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	0.24 (0.2 to 0.4)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	0.68 (0.2 to 0.9)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	0.243 (0.207 to 0.248)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population

End point title	tlast for belantamab mafodotin (Cys-mcMMAF), Treatment A - PK population[53]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose Cycle 1 Day 1 to pre-dose Cycle 1 Day 15

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	14
Units: Hour				
median (full range (min-max))	165.567 (25.50 to 357.02)	120.283 (49.97 to 191.58)	336.900 (94.40 to 360.17)	166.167 (2.08 to 239.17)

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for belantamab mafodotin (Cys-mcMMAF) Treatment B - PK population

End point title	Cmax for belantamab mafodotin (Cys-mcMMAF) Treatment B - PK population[54]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	12	12	12
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	0.73 (± 29.88)	0.75 (± 68.94)	1.03 (± 52.77)	1.29 (± 38.95)
CYCLE 1 DAY 8	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	9
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
CYCLE 1 DAY 1	0.65 (± 87.99)	1.15 (± 57.18)	1.03 (± 38.56)	1.09 (± 40.30)
CYCLE 1 DAY 8	0.58 (± 87.48)	88888 (± 88888)	0.86 (± 64.55)	88888 (± 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-168h) for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population

End point title	AUC(0-168h) for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population[55]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-dose, 0, 2, and 24 Hours Post Dose on Cycle 1 Day 1, Cycle 1 Day 4; and Cycle 1 Day 7

Notes:

[55] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	9	10	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	89.05 (± 41.52)	52.82 (± 96.74)	81.17 (± 31.46)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population

End point title	Tmax for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population[56]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8

Notes:

[56] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	12	12	12
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	22.225 (22.07 to 24.77)	24.475 (1.00 to 25.75)	23.092 (22.00 to 25.95)	22.442 (1.17 to 74.02)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	9
Units: Hour				
median (full range (min-max))				
CYCLE 1 DAY 1	24.083 (19.30 to 77.37)	24.083 (2.07 to 25.25)	24.583 (22.97 to 70.28)	24.667 (21.85 to 25.72)
CYCLE 1 DAY 8	24.000 (0.92 to 25.30)	88888 (88888 to 88888)	23.717 (2.58 to 25.60)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population

End point title	tlast for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population[57]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. Tlast is the time of last observed quantifiable concentration of belantamab mafodotin in Cycle 1 which extended beyond protocol defined duration for some participants across treatment groups.

End point type	Secondary

End point timeframe:

Pre-Dose Cycle 1 Day 1 to pre-dose 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Hour				
median (full range (min-max))	85.542 (68.57 to 262.25)	239.800 (72.33 to 243.90)	237.992 (70.58 to 265.82)	93.942 (67.95 to 242.77)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Hour				
median (full range (min-max))	241.283	237.425	240.675	171.567 (2.00

(146.33 to 527.50)	(70.53 to 241.58)	(237.55 to 503.73)	to 266.87)

Statistical analyses

No statistical analyses for this end point

Secondary: C-EOI for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population

End point title	C-EOI for belantamab mafodotin (Cys-mcMMAF), Treatment B - PK population[58]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected. 77777= As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0, 2 and 24 Hour on Cycle 1 Day 1 and Cycle 1 Day 8; Pre-Dose and Post-Dose on Week 4 Day 1, Week 7 Day 1, Week 7 Day 8, Week 7 Day 11, Week 10 Day 1, Week 10 Day 8, Week 13 Day 1, Week 13 Day 8

Notes:

[58] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	0.29 (0.1 to 0.5)	0.21 (0.1 to 2.7)	0.28 (0.2 to 0.6)	0.32 (0.1 to 1.4)
CYCLE 1 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 4 DAY 1	88888 (88888 to 88888)	0.19 (0.1 to 0.4)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 1	0.20 (0.1 to 0.4)	0.21 (0.1 to 0.3)	0.17 (0.1 to 0.2)	0.31 (0.1 to 0.9)
WEEK 7 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 7 DAY 11	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 10 DAY 1	88888 (88888 to 88888)	88888 (88888 to 88888)	0.236 (0.188 to 0.238)	77777 (77777 to 77777)
WEEK 10 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 13 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	0.222 (0.118 to 0.240)	77777 (77777 to 77777)

WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	17	11	15
Units: ug/mL				
median (full range (min-max))				
CYCLE 1 DAY 1	0.19 (0.1 to 0.7)	0.29 (0.1 to 0.8)	0.27 (0.1 to 0.8)	0.39 (0.2 to 0.6)
CYCLE 1 DAY 8	0.27 (0.1 to 1.5)	88888 (88888 to 88888)	0.40 (0.2 to 0.9)	88888 (88888 to 88888)
WEEK 4 DAY 1	0.21 (0.1 to 0.4)	0.35 (0.1 to 1.5)	0.26 (0.2 to 0.6)	0.35 (0.2 to 0.9)
WEEK 7 DAY 1	0.27 (0.1 to 0.4)	0.24 (0.1 to 0.9)	0.20 (0.2 to 0.4)	0.36 (0.2 to 0.4)
WEEK 7 DAY 8	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)
WEEK 7 DAY 11	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)
WEEK 10 DAY 1	77777 (77777 to 77777)	88888 (88888 to 88888)	77777 (77777 to 77777)	99999 (99999 to 99999)
WEEK 10 DAY 8	77777 (77777 to 77777)	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)
WEEK 13 DAY 1	88888 (88888 to 88888)	77777 (77777 to 77777)	77777 (77777 to 77777)	0.24 (0.1 to 0.3)
WEEK 13 DAY 8	88888 (88888 to 88888)	88888 (88888 to 88888)	77777 (77777 to 77777)	88888 (88888 to 88888)

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for Lenalidomide (25 mg), Treatment A - PK population

End point title	Cmax for Lenalidomide (25 mg), Treatment A - PK

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2, 4 and 24 hours on Cycle 1 Day 1 post lenalidomide dose

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SINGLE +	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	13	
Units: ug/mL				
geometric mean (geometric coefficient of variation)	382.16 (± 54.52)	331.53 (± 17.91)	283.08 (± 36.55)	

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-24h) for Lenalidomide (25 mg), Treatment A - PK population

End point title	AUC(0-24h) for Lenalidomide (25 mg), Treatment A - PK population[60]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2, 4 and 24 hours on Cycle 1 Day 1 post lenalidomide dose

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SINGLE +	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	3	8	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	2247.36 (± 65.76)	1577.62 (± 21.66)	2117.26 (± 38.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-4h) for Lenalidomide (25 mg), Treatment A - PK population

End point title	AUC (0-4h) for Lenalidomide (25 mg), Treatment A - PK population[61]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2 and 4 hours on Cycle 1 Day 1 post lenalidomide dose

Notes:

[61] - 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: #Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SINGLE +	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	3	9	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	812.22 (± 105.88)	870.92 (± 19.36)	620.10 (± 44.84)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for Lenalidomide (25 mg), Treatment A - PK population

End point title	Tmax for Lenalidomide (25 mg), Treatment A - PK

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2, 4 and 24 hours on Cycle 1 Day 1 post lenalidomide dose

Notes:

[62] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SINGLE +	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	13	
Units: Hour				
median (full range (min-max))	0.967 (0.47 to 4.00)	1.417 (0.93 to 2.00)	3.767 (1.92 to 4.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for Lenalidomide (25 mg), Treatment A - PK population

End point title	tlast for Lenalidomide (25 mg), Treatment A - PK population[63]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods.

End point type	Secondary

End point timeframe:

Pre-Dose, Post dose on Cycle 1 Day 1

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SINGLE +	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	4	13	
Units: Hour				
median (full range (min-max))	20.750 (3.80 to 24.00)	4.000 (3.77 to 22.57)	22.050 (3.75 to 23.55)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for Lenalidomide (10 mg), Treatment A - PK population

End point title	Cmax for Lenalidomide (10 mg), Treatment A - PK

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2, 4 and 24 hours on Cycle 1 Day 1 post lenalidomide dose

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 2.5mg/kg SINGLE +		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: ug/mL				
geometric mean (geometric coefficient of variation)	193.06 (± 36.86)	88888 (± 88888)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-24h) for Lenalidomide (10 mg), Treatment A - PK population

End point title	AUC(0-24h) for Lenalidomide (10 mg), Treatment A - PK population[65]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2, 4 and 24 hours on Cycle 1 Day 1 post lenalidomide dose

Notes:

[65] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 2.5mg/kg SINGLE +		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	1		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	1660.82 (± 22.40)	88888 (± 88888)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-4h) for Lenalidomide (10 mg), Treatment A - PK population

End point title	AUC (0-4h) for Lenalidomide (10 mg), Treatment A - PK population[66]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-

compartmental methods. 88888 = As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2 and 4 hours on Cycle 1 Day 1 post lenalidomide dose

Notes:

[66] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 2.5mg/kg SINGLE +		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)	486.46 (± 41.84)	88888 (± 88888)		

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for Lenalidomide (10 mg), Treatment A - PK population

End point title	Tmax for Lenalidomide (10 mg), Treatment A - PK

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, 0.5, 1, 2, 4 and 24 hours on Cycle 1 Day 1 post lenalidomide dose

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 2.5mg/kg SINGLE +		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Hour				
median (full range (min-max))	2.000 (0.53 to 3.80)	88888 (88888 to 88888)		

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for Lenalidomide (10 mg), Treatment A - PK population

End point title	tlast for Lenalidomide (10 mg), Treatment A - PK population[68]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = As pre-specified in the SAP, data is not reported if the number of participants analyzed is less than 3.

End point type	Secondary

End point timeframe:

Pre-Dose, Post dose on Cycle 1 Day 1

Notes:

[68] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 2.5mg/kg SINGLE +		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Hour				
median (full range (min-max))	21.583 (21.27 to 23.68)	88888 (88888 to 88888)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-72h) for Bortezomib, Treatment B - PK population

End point title	AUC (0-72h) for Bortezomib, Treatment B - PK population[69]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-dose, 5 minute, 0.25, 0.5, 1, 2, 4, 6, 10, 24, 48 and 72 hour post bortezomib dose

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	14	13	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Intravenous	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	
Subcutaneous	95.10 (± 21.71)	73.03 (± 30.79)	73.06 (± 21.57)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax for Bortezomib, Treatment B - PK population

End point title	Cmax for Bortezomib, Treatment B - PK population[70]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post-Dose 0.5, 1, 2, 4 and 24 Hour on Cycle 1 Day 1

Notes:

[70] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	15	15	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
INTRAVENOUS	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	
SUBCUTANEOUS	14.45 (± 50.16)	14.89 (± 44.03)	15.88 (± 42.07)	

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-t) for Bortezomib, Treatment B - PK population

End point title	AUC (0-t) for Bortezomib, Treatment B - PK population[71]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-dose, 5 minute, 0.25, 0.5, 1, 2, 4, 6, 10, 24, 48 and 72 hour post bortezomib dose

Notes:

[71] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	15	15	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Intravenous	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	
Subcutaneous	89.48 (± 25.50)	69.51 (± 31.87)	71.70 (± 26.79)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax for Bortezomib, Treatment B - PK population

End point title	Tmax for Bortezomib, Treatment B - PK population[72]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-dose, 5 minute, 0.25, 0.5, 1, 2, 4, 6, 10, 24, 48 and 72 hour post bortezomib dose

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	15	15	
Units: Hour				
median (full range (min-max))				
Intravenous	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	
Subcutaneous	0.533 (0.10 to 1.07)	0.517 (0.25 to 1.00)	0.500 (0.08 to 1.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: tlast for Bortezomib, Treatment B - PK population

End point title	tlast for Bortezomib, Treatment B - PK population[73]

End point description:

Blood samples were collected for PK analysis. PK parameter was determined using standard non-compartmental methods. 88888 = Data was not collected.

End point type	Secondary

End point timeframe:

Pre-Dose, Post dose on Cycle 1 Day 3

Notes:

[73] - 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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	11	16	15	
Units: Hour				
median (full range (min-max))				
Intravenous	88888 (88888 to 88888)	88888 (88888 to 88888)	88888 (88888 to 88888)	
Subcutaneous	68.867 (44.07 to 72.00)	68.392 (44.35 to 73.10)	48.000 (46.17 to 75.65)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with anti-drug antibodies (ADAs) against belantamab mafodotin - All treated population

End point title	Number of participants with anti-drug antibodies (ADAs) against belantamab mafodotin - All treated population

End point description:

Serum samples were collected and tested for the presence of antibodies against belantamab mafodotin.

End point type	Secondary

End point timeframe:

Up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	3	13	15
Units: Participants				
Baseline	0	0	0	1
End of Treatment	0	0	0	0

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Baseline	0	0	0	0
End of Treatment	0	0	0	0

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	18	11	16
Units: Participants				
Baseline	1	0	1	0
End of Treatment	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Ocular Surface Disease Index (OSDI) Total Scores - All treated population

End point title	Change from Baseline in Ocular Surface Disease Index (OSDI) Total Scores - All treated population

End point description:

The OSDI is a 12-item questionnaire designed to assess both the frequency of dry eye symptoms and their impact on vision-related functioning. OSDI consist of three subscales (ocular symptoms: item 1-3; visual related function: item 4-9; environmental triggers: item 10-12). Each item will be graded on a scale of 0 (none of the time or lower disability) to 4 (all of the time or greater disability) with total scores ranging from 0 (no disability) to 100 (complete disability). The total OSDI score was calculated as (sum of scores for all questions answered*100) divided by (total number of questions answered*4). Higher scores indicated greater disability. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Change from Baseline was calculated by subtracting Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	4	11	12
Units: Score on scale				
arithmetic mean (standard deviation)				
Baseline (Day 1)	11.1 (± 7.58)	0.8 (± 1.56)	7.8 (± 9.30)	11.4 (± 14.26)
End of Treatment	-5.2 (± 4.42)	0.6 (± 4.10)	6.9 (± 12.03)	2.2 (± 7.19)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	12	9
Units: Score on scale				
arithmetic mean (standard deviation)				
Baseline (Day 1)	10.8 (± 17.20)	2.4 (± 2.79)	7.8 (± 9.94)	8.0 (± 5.66)

End of Treatment	15.2 (± 35.94)	15.9 (± 14.80)	18.7 (± 34.95)	29.3 (± 39.18)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	15	9	14
Units: Score on scale				
arithmetic mean (standard deviation)				
Baseline (Day 1)	12.4 (± 16.42)	6.3 (± 7.71)	8.6 (± 13.61)	3.3 (± 5.58)
End of Treatment	6.1 (± 8.59)	14.4 (± 23.26)	48.3 (± 27.42)	19.3 (± 14.41)

Statistical analyses

No statistical analyses for this end point

Secondary: Titers of ADAs Against Belantamab Mafodotin - All treated population

End point title	Titers of ADAs Against Belantamab Mafodotin - All treated population[74]

End point description:

Confirmed positive ADA samples were further analyzed to obtain the titer of the antibodies. Titer is defined as the reciprocal of the highest dilution that yield results at or above the plate-based titer cut point x MRD.

End point type	Secondary

End point timeframe:

Up to approximately 4.5 years

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: Per objective of this endpoint, only analysis of belantamab mafodotin was planned to be presented.

End point values	Belantamab mafodotin 2.5mg/kg SINGLE +	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	1	1	
Units: Titers				
median (full range (min-max))	100 (100 to 100)	100 (100 to 100)	100 (100 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) Overall Composite Scores - All treated population

End point title	Change from Baseline in the National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25) Overall Composite Scores - All treated population

End point description:

The NEI-VFQ-25 consisted of a base set of 25 vision-targeted questions representing 11 vision-related constructs, plus an additional single-item general health rating question to assess the patient's perception of vision-related functioning and vision-related quality of life. Items were coded to a 0 to 100 scale and were averaged to calculate domains. The composite score ranges from 0 (worst score) to 100 (best score), with higher scores indicating better vision-related functioning. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Change from Baseline was calculated by subtracting Baseline value from the post-dose visit value. 77777 = standard deviation (SD) could not be calculated for a single participant.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	3	11	12
Units: Score on scale				
arithmetic mean (standard deviation)				
Baseline (Day 1)	85.1 (± 11.42)	89.0 (± 18.43)	91.9 (± 10.88)	91.0 (± 11.35)
End of Treatment	0.2 (± 13.53)	12.9 (± 22.42)	-4.5 (± 4.04)	-1.9 (± 3.43)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	8	9	8
Units: Score on scale				
arithmetic mean (standard deviation)				
Baseline (Day 1)	88.0 (± 16.92)	95.5 (± 4.70)	96.2 (± 5.20)	95.3 (± 4.60)
End of Treatment	1.1 (± 19.48)	-8.4 (± 13.65)	-18.3 (± 19.96)	-26.0 (± 31.54)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	11	7	10

Units: Score on scale				
arithmetic mean (standard deviation)				
Baseline (Day 1)	90.4 (± 7.67)	94.1 (± 8.33)	93.2 (± 7.13)	94.7 (± 5.59)
End of Treatment	1.3 (± 77777)	-13.2 (± 25.00)	-48.9 (± 2.35)	-11.5 (± 15.39)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Symptomatic AEs Measured by Patient-reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) - All treated population

End point title	Number of Participants With Symptomatic AEs Measured by Patient-reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) - All treated population

End point description:

The PRO-CTCAE is a patient-reported outcome measure developed to evaluate symptomatic toxicity in participants on cancer clinical trials. It included item library of 124 items representing 78 symptomatic toxicities drawn from the CTCAE like Anxious, Blurred Vision, Chills, Concentration, Constipation, Cough, Decreased Appetite, Discouraged, Dizziness, Fatigue, Heart Palpitations, Insomnia, Memory, Mouth/Throat Sores, Nausea, Nosebleed, Numbness & Tingling, Pain, Ringing In Ears, Shortness Of Breath, Vomiting and Watery Eyes. Number of participants with symptomatic AEs are presented.

End point type	Secondary

End point timeframe:

Up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Anxious	8	4	13	13
Blurred Vision	0	0	0	0
Chills	8	4	13	13
Concentration	0	0	0	0
Constipation	0	0	0	0
Cough	0	0	0	0
Decreased Appetite	0	0	0	0
Discouraged	8	4	13	13
Dizziness	0	0	0	0
Fatigue	0	0	0	0
Heart Palpitations	8	4	13	13
Insomnia	0	0	0	0
Memory	0	0	0	0
Mouth/Throat Sores	0	0	0	0

Nausea	8	4	13	13
Nosebleed	8	4	13	13
Numbness & tingling	0	0	0	0
Pain	8	4	13	13
Ringing In Ears	0	0	0	0
Shortness Of Breath	0	0	0	0
Vomiting	8	4	13	13
Watery Eyes	0	0	0	0

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Anxious	8	12	12	11
Blurred Vision	0	0	0	0
Chills	8	12	12	11
Concentration	0	0	0	0
Constipation	0	0	0	0
Cough	0	0	0	0
Decreased Appetite	0	0	0	0
Discouraged	8	12	12	11
Dizziness	0	0	0	0
Fatigue	0	0	0	0
Heart Palpitations	8	12	12	11
Insomnia	0	0	0	0
Memory	0	0	0	0
Mouth/Throat Sores	0	0	0	0
Nausea	8	12	12	11
Nosebleed	8	12	12	11
Numbness & tingling	0	0	0	0
Pain	8	12	12	11
Ringing In Ears	0	0	0	0
Shortness Of Breath	0	0	0	0
Vomiting	8	12	12	11
Watery Eyes	0	0	0	0

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Anxious	11	17	10	15

Blurred Vision	0	0	0	0
Chills	11	17	10	15
Concentration	0	0	0	0
Constipation	0	0	0	0
Cough	0	0	0	0
Decreased Appetite	0	0	0	0
Discouraged	11	17	10	15
Dizziness	0	0	0	0
Fatigue	0	0	0	0
Heart Palpitations	11	17	10	15
Insomnia	0	0	0	0
Memory	0	0	0	0
Mouth/Throat Sores	0	0	0	0
Nausea	11	17	10	15
Nosebleed	11	17	10	15
Numbness & tingling	0	0	0	0
Pain	11	17	10	15
Ringing In Ears	0	0	0	0
Shortness Of Breath	0	0	0	0
Vomiting	11	17	10	15
Watery Eyes	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with AEs of special interest (AESI) - All treated population

End point title	Number of participants with AEs of special interest (AESI) - All treated population

End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. Number of participants with AESI for belantamab mafodotin (corneal events, thrombocytopenia and infusion related reactions) are presented.

End point type	Secondary

End point timeframe:

Up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Corneal Events	9	3	12	11
Thrombocytopenia	4	2	7	11

Infusion Related Reactions	1	0	2	3

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Corneal Events	9	12	12	12
Thrombocytopenia	9	12	10	11
Infusion Related Reactions	0	2	1	2

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Corneal Events	10	17	10	16
Thrombocytopenia	11	13	12	14
Infusion Related Reactions	2	3	3	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Worst-case Change From Baseline in Best Corrected Visual Acuity Test (BCVA) Scores - All treated population

End point title	Number of Participants With Worst-case Change From Baseline in Best Corrected Visual Acuity Test (BCVA) Scores - All treated population

End point description:

BCVA score was assessed individually for each eye. BCVA score was calculated based on the Logarithm of the Minimum Angle of Resolution (logMAR score). Any worst-case change from baseline categories are presented for right and left eyes. BCVA test scores were categorized as no change/improved vision, possible worsened vision and definite worsened vision. No change/improved vision was defined as a change from baseline <0.12 logMAR score; a possible worsened vision was defined as a change from baseline >=0.12 to <0.3 logMAR score; a definite worsened vision was defined as a change from baseline >=0.3 logMAR score. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Change from Baseline was calculated by subtracting Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	4	13	14
Units: Participants				
Right Eye|No change/improved vision	2	2	5	3
Left Eye|No change/improved vision	2	1	2	4
Right Eye|Possible worsened vision	3	0	0	2
Left Eye|Possible worsened vision	2	0	2	1
Right Eye|Definite worsened vision	4	2	8	9
Left Eye|Definite worsened vision	5	3	9	9

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	12	12
Units: Participants				
Right Eye|No change/improved vision	4	3	2	2
Left Eye|No change/improved vision	4	1	2	5
Right Eye|Possible worsened vision	2	2	0	4
Left Eye|Possible worsened vision	0	3	5	1
Right Eye|Definite worsened vision	5	7	10	6
Left Eye|Definite worsened vision	7	8	5	6

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	18	11	16
Units: Participants				
Right Eye|No change/improved vision	4	3	2	1
Left Eye|No change/improved vision	4	3	3	2
Right Eye|Possible worsened vision	2	2	5	5
Left Eye|Possible worsened vision	2	3	2	6
Right Eye|Definite worsened vision	6	13	4	10
Left Eye|Definite worsened vision	6	12	6	8

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Worst-case post-baseline Change in BCVA Scores by Snellen results - All treated population

End point title	Number of Participants With Worst-case post-baseline Change in BCVA Scores by Snellen results - All treated population

End point description:

BCVA score was assessed individually for better seeing eye and worse seeing eye. BCVA score was calculated based on the Logarithm of the Minimum Angle of Resolution (logMAR score). Any worst-case change post baseline categories are presented for better eye and worse eye. BCVA test scores by Snellen results were categorized as improved BCVA, <= 2 lines decline in visual acuity from baseline, >= 3 lines decline in visual acuity from baseline. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Change from Baseline was calculated by subtracting Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	4	13	14
Units: Participants				
Better Eye|Improved BCVA	0	0	1	0
Worse Eye|Improved BCVA	0	0	1	0
Better Eye|<=2 Lines decline	8	3	9	11
Worse Eye|<=2 Lines decline	5	3	4	5
Better Eye|>=3 Lines decline	1	1	3	3
Worse Eye|>=3 Lines decline	4	1	8	9

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	12	12
Units: Participants				

Better Eye|Improved BCVA	0	0	0	0
Worse Eye|Improved BCVA	1	0	0	0
Better Eye|<=2 Lines decline	7	7	10	8
Worse Eye|<=2 Lines decline	6	5	8	7
Better Eye|>=3 Lines decline	4	5	2	4
Worse Eye|>=3 Lines decline	4	7	4	5

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	18	11	16
Units: Participants				
Better Eye|Improved BCVA	1	1	0	0
Worse Eye|Improved BCVA	1	0	0	0
Better Eye|<=2 Lines decline	9	8	9	12
Worse Eye|<=2 Lines decline	6	6	7	8
Better Eye|>=3 Lines decline	2	9	2	4
Worse Eye|>=3 Lines decline	5	12	4	8

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Post-baseline Decline in BCVA to Light Perception or no Light Perception - All treated population

End point title	Number of Participants With Post-baseline Decline in BCVA to Light Perception or no Light Perception - All treated population

End point description:

Number of participants with a Decline in BCVA to 'Light Perception (LP)' or 'No Light Perception (NLP)' due to a Corneal Event Anytime Post-Baseline are presented. BCVA score was assessed individually for each eye. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Number of participants analyzed were who have any post-baseline BCVA score, where the Visual Acuity is due to corneal findings.

End point type	Secondary

End point timeframe:

Baseline and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	3	10	11
Units: Participants				

Left Eye, LP	0	0	0	0
Left Eye, NLP	0	0	0	0
Right Eye, LP	0	0	1	0
Right Eye, NLP	0	0	0	0

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	12	11
Units: Participants				
Left Eye, LP	0	0	0	0
Left Eye, NLP	0	0	0	0
Right Eye, LP	0	0	0	0
Right Eye, NLP	0	0	0	0

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	11	8	10
Units: Participants				
Left Eye, LP	0	0	0	0
Left Eye, NLP	0	0	0	0
Right Eye, LP	0	0	0	0
Right Eye, NLP	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Shift in Corneal Epithelium Findings From no (Baseline) to Yes (Worst Post-Baseline) - All treated population

End point title	Number of Participants With Shift in Corneal Epithelium Findings From no (Baseline) to Yes (Worst Post-Baseline) - All treated population

End point description:

Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Corneal epithelium findings like active edema, active opacity, corneal neovascularization (CN), corneal ulcer, epithelial microcystic edema (EME) and subepithelial were performed using a slit lamp. Number of participants with shift in corneal epithelium findings from no (Baseline) to yes (worst post-Baseline) are presented.

End point type	Secondary

End point timeframe:
Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	16
Units: Participants				
Active Edema, Right Eye	0	0	0	2
Active Edema, Left Eye	0	0	1	1
Active Opacity, Right Eye	0	0	0	3
Active Opacity, Left Eye	0	1	1	2
Corneal Neovascularization, Right Eye	0	0	0	0
Corneal Neovascularization, Left Eye	0	0	0	0
Corneal Ulcer, Right Eye	0	0	1	0
Corneal Ulcer, Left Eye	0	0	1	0
Epithelial Microcystic Edema, Right Eye	2	1	3	6
Epithelial Microcystic Edema, Left Eye	2	2	2	6
Subepithelial Haze, Right Eye	3	1	5	8
Subepithelial Haze, Left Eye	3	2	6	9

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Active Edema, Right Eye	0	0	0	0
Active Edema, Left Eye	0	0	0	0
Active Opacity, Right Eye	0	0	0	0
Active Opacity, Left Eye	0	0	0	0
Corneal Neovascularization, Right Eye	0	0	0	0
Corneal Neovascularization, Left Eye	0	0	0	0
Corneal Ulcer, Right Eye	0	0	0	0
Corneal Ulcer, Left Eye	0	0	1	0
Epithelial Microcystic Edema, Right Eye	2	3	3	3
Epithelial Microcystic Edema, Left Eye	4	3	4	2
Subepithelial Haze, Right Eye	5	8	3	6
Subepithelial Haze, Left Eye	6	9	5	4

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	18	12	16
Units: Participants				
Active Edema, Right Eye	0	2	0	0
Active Edema, Left Eye	0	0	0	0
Active Opacity, Right Eye	0	3	0	1
Active Opacity, Left Eye	0	2	0	1
Corneal Neovascularization, Right Eye	2	0	0	2
Corneal Neovascularization, Left Eye	0	0	0	2
Corneal Ulcer, Right Eye	2	0	0	0
Corneal Ulcer, Left Eye	0	0	0	0
Epithelial Microcystic Edema, Right Eye	3	9	3	9
Epithelial Microcystic Edema, Left Eye	4	8	3	9
Subepithelial Haze, Right Eye	5	9	8	9
Subepithelial Haze, Left Eye	4	10	8	10

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Worse Grade Post-baseline Punctate Keratopathy Findings - All treated population

End point title	Number of Participants With Worse Grade Post-baseline Punctate Keratopathy Findings - All treated population

End point description:

Participants with worse grade 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 (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	4	13	14
Units: Participants				
Right Eye|None	2	0	2	0
Left Eye|None	1	0	2	0
Worst eye|None	1	0	2	0
Right Eye|Mild	1	2	5	6
Left Eye|Mild	3	2	1	4

Worst eye|Mild	1	2	1	4
Right Eye|Moderate	5	2	3	6
Left Eye|Moderate	4	2	9	6
Worst eye|Moderate	6	2	7	6
Right Eye|Severe	1	0	3	2
Left Eye|Severe	1	0	1	4
Worst eye|Severe	1	0	3	4

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	12	12	12
Units: Participants				
Right Eye|None	0	1	0	0
Left Eye|None	2	2	0	0
Worst eye|None	0	1	0	0
Right Eye|Mild	5	3	5	1
Left Eye|Mild	5	3	5	2
Worst eye|Mild	5	3	5	1
Right Eye|Moderate	5	7	4	7
Left Eye|Moderate	3	5	5	5
Worst eye|Moderate	5	6	3	6
Right Eye|Severe	1	1	3	4
Left Eye|Severe	1	2	2	5
Worst eye|Severe	1	2	4	5

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	18	11	16
Units: Participants				
Right Eye|None	2	0	1	1
Left Eye|None	2	0	1	0
Worst eye|None	2	0	1	0
Right Eye|Mild	2	3	2	2
Left Eye|Mild	1	3	2	2
Worst eye|Mild	1	2	2	2
Right Eye|Moderate	5	9	6	9
Left Eye|Moderate	7	9	6	10
Worst eye|Moderate	6	10	6	9
Right Eye|Severe	3	6	2	4
Left Eye|Severe	2	6	2	4
Worst eye|Severe	3	6	2	5

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30-item Core Module (EORTC QLQ-C30) Score - All treated population

End point title	Change From Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30-item Core Module (EORTC QLQ-C30) Score - All treated population

End point description:

The EORTC QLQ-C30 includes 30-items with single and multi-item scales. These included five functional scales (physical functioning [PF], role functioning [RF], cognitive functioning [CF], emotional functioning [EF] and social functioning [SF]), three symptom scales (fatigue, pain and nausea/vomiting [N/V]), a global health status (GHS)/ Quality-of-Life (QoL) scale, and six single items (constipation, diarrhea, insomnia, dyspnea, appetite loss [AL] and financial difficulties [FD]). Response options are 1 to 4. Scores were averaged and transformed to 0 to 100, a high score for functional scales/ GHS/QoL represent better functioning ability or health-related quality-of-life (HRQoL), whereas a high score for symptom scales/ single items represent significant symptomatology. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Change from Baseline (CFB) was calculated by subtracting Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	3	10	8
Units: Score on scale				
arithmetic mean (standard deviation)				
GHS/QoL, Baseline (Day 1)	65.8 (± 25.29)	69.4 (± 31.55)	58.3 (± 14.16)	60.4 (± 13.18)
GHS/QoL, CFB to EoT	-50.0 (± 22.05)	4.2 (± 17.68)	-4.2 (± 14.43)	-16.7 (± 18.00)
PF, Baseline (Day 1)	67.3 (± 23.82)	88.9 (± 13.88)	78.7 (± 15.65)	73.3 (± 21.97)
PF, CFB to EoT	-17.8 (± 48.23)	13.3 (± 18.86)	-6.7 (± 24.94)	0.0 (± 33.11)
RF, Baseline (Day 1)	66.7 (± 30.43)	88.9 (± 19.25)	76.7 (± 22.50)	72.9 (± 29.46)
RF, CFB to EoT	-22.2 (± 69.39)	16.7 (± 23.57)	8.3 (± 34.69)	4.2 (± 34.36)
EF, Baseline (Day 1)	76.7 (± 25.40)	86.1 (± 4.81)	77.5 (± 18.02)	76.0 (± 16.93)
EF, CFB to EoT	5.6 (± 29.27)	-12.5 (± 5.89)	0.0 (± 0.00)	10.4 (± 15.77)
CF, Baseline (Day 1)	75.0 (± 16.20)	88.9 (± 9.62)	71.7 (± 24.91)	72.9 (± 21.71)
CF, CFB to EoT	-16.7 (± 44.10)	8.3 (± 11.79)	16.7 (± 19.25)	12.5 (± 20.97)

SF, Baseline (Day 1)	71.7 (± 26.12)	88.9 (± 19.25)	80.0 (± 18.92)	77.1 (± 21.71)
SF, CFB to EoT	-27.8 (± 63.10)	8.3 (± 11.79)	0.0 (± 23.57)	-12.5 (± 36.96)
Fatigue, Baseline (Day 1)	46.7 (± 23.89)	25.9 (± 16.97)	31.1 (± 8.76)	38.9 (± 19.70)
Fatigue, CFB to EoT	3.7 (± 35.72)	-11.1 (± 15.71)	5.6 (± 6.42)	2.8 (± 24.64)
N/V, Baseline (Day 1)	11.7 (± 15.81)	0.0 (± 0.00)	11.7 (± 15.81)	2.1 (± 5.89)
N/V, CFB to EoT	11.1 (± 41.94)	0.0 (± 0.00)	4.2 (± 8.33)	-4.2 (± 8.33)
Pain, Baseline (Day 1)	46.7 (± 35.83)	22.2 (± 25.46)	36.7 (± 24.60)	37.5 (± 31.81)
Pain, CFB to EoT	0.0 (± 16.67)	-16.7 (± 47.14)	-12.5 (± 15.96)	-25.0 (± 50.00)
Dyspnoea, Baseline (Day 1)	33.3 (± 35.14)	11.1 (± 19.25)	13.3 (± 17.21)	12.5 (± 17.25)
Dyspnoea, CFB to EoT	33.3 (± 33.33)	-16.7 (± 23.57)	25.0 (± 31.91)	16.7 (± 19.25)
Insomnia, Baseline (Day 1)	40.0 (± 26.29)	44.4 (± 38.49)	33.3 (± 27.22)	29.2 (± 21.36)
Insomnia, CFB to EoT	0.0 (± 33.33)	0.0 (± 47.14)	-16.7 (± 19.25)	0.0 (± 27.22)
AL, Baseline (Day 1)	23.3 (± 27.44)	0.0 (± 0.00)	6.7 (± 14.05)	25.0 (± 23.57)
AL, CFB to EoT	22.2 (± 19.25)	16.7 (± 23.57)	16.7 (± 19.25)	-16.7 (± 19.25)
Constipation, Baseline (Day 1)	20.0 (± 28.11)	0.0 (± 0.00)	6.7 (± 14.05)	12.5 (± 17.25)
Constipation, CFB to EoT	0.0 (± 0.00)	16.7 (± 23.57)	16.7 (± 33.33)	16.7 (± 33.33)
Diarrhoea, Baseline (Day 1)	6.7 (± 14.05)	0.0 (± 0.00)	16.7 (± 23.57)	8.3 (± 15.43)
Diarrhoea, CFB to EoT	22.2 (± 19.25)	33.3 (± 47.14)	8.3 (± 31.91)	8.3 (± 16.67)
FD, Baseline (Day 1)	30.0 (± 33.15)	11.1 (± 19.25)	30.0 (± 36.68)	0.0 (± 0.00)
FD, CFB to EoT	33.3 (± 57.74)	0.0 (± 0.00)	8.3 (± 31.91)	0.0 (± 0.00)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	11	11
Units: Score on scale				
arithmetic mean (standard deviation)				
GHS/QoL, Baseline (Day 1)	56.2 (± 23.33)	67.6 (± 9.72)	63.6 (± 20.84)	56.1 (± 20.78)
GHS/QoL, CFB to EoT	-10.0 (± 34.05)	-8.3 (± 11.79)	0.0 (± 13.94)	-14.6 (± 25.88)
PF, Baseline (Day 1)	75.0 (± 15.60)	84.4 (± 17.95)	85.5 (± 17.34)	70.9 (± 25.69)
PF, CFB to EoT	-5.3 (± 22.80)	-10.0 (± 14.14)	-1.1 (± 9.81)	-12.5 (± 27.93)
RF, Baseline (Day 1)	68.1 (± 21.86)	72.2 (± 22.05)	81.8 (± 24.10)	57.6 (± 36.03)
RF, CFB to EoT	-6.7 (± 25.28)	-8.3 (± 35.36)	-11.1 (± 27.22)	0.0 (± 32.12)
EF, Baseline (Day 1)	70.8 (± 20.87)	94.4 (± 7.22)	73.5 (± 25.50)	68.9 (± 28.89)
EF, CFB to EoT	3.3 (± 33.64)	-16.7 (± 23.57)	0.0 (± 11.79)	-6.3 (± 25.49)
CF, Baseline (Day 1)	81.9 (± 19.41)	87.0 (± 13.89)	81.8 (± 17.41)	74.2 (± 15.57)
CF, CFB to EoT	-10.0 (± 25.28)	-16.7 (± 23.57)	2.8 (± 6.80)	0.0 (± 17.82)
SF, Baseline (Day 1)	76.4 (± 20.67)	83.3 (± 18.63)	77.3 (± 28.16)	71.2 (± 28.95)

SF, CFB to EoT	-6.7 (± 25.28)	-16.7 (± 0.00)	-11.1 (± 22.77)	-27.1 (± 36.66)
Fatigue, Baseline (Day 1)	34.3 (± 19.22)	28.4 (± 21.60)	29.3 (± 13.40)	34.3 (± 26.51)
Fatigue, CFB to EoT	13.3 (± 28.76)	-11.1 (± 15.71)	-3.7 (± 13.46)	16.7 (± 33.60)
N/V, Baseline (Day 1)	8.3 (± 15.08)	3.7 (± 7.35)	4.5 (± 7.78)	1.5 (± 5.03)
N/V, CFB to EoT	-6.7 (± 30.28)	-8.3 (± 11.79)	5.6 (± 17.21)	6.3 (± 12.40)
Pain, Baseline (Day 1)	41.7 (± 26.11)	24.1 (± 29.00)	28.8 (± 25.92)	34.8 (± 34.52)
Pain, CFB to EoT	20.0 (± 36.13)	-16.7 (± 23.57)	-5.6 (± 8.61)	12.5 (± 30.54)
Dyspnoea, Baseline (Day 1)	22.2 (± 25.95)	11.1 (± 16.67)	15.2 (± 17.41)	33.3 (± 36.51)
Dyspnoea, CFB to EoT	0.0 (± 23.57)	0.0 (± 0.00)	-5.6 (± 13.61)	12.5 (± 39.59)
Insomnia, Baseline (Day 1)	36.1 (± 33.21)	25.9 (± 14.70)	27.3 (± 25.03)	33.3 (± 33.33)
Insomnia, CFB to EoT	-6.7 (± 27.89)	-16.7 (± 23.57)	5.6 (± 25.09)	8.3 (± 23.57)
AL, Baseline (Day 1)	13.9 (± 22.29)	7.4 (± 14.70)	12.1 (± 16.82)	9.1 (± 15.57)
AL, CFB to EoT	0.0 (± 33.33)	16.7 (± 23.57)	0.0 (± 0.00)	-4.2 (± 21.36)
Constipation, Baseline (Day 1)	16.7 (± 26.59)	11.1 (± 16.67)	12.1 (± 16.82)	9.1 (± 15.57)
Constipation, CFB to EoT	0.0 (± 0.00)	0.0 (± 47.14)	0.0 (± 0.00)	4.2 (± 21.36)
Diarrhoea, Baseline (Day 1)	19.4 (± 22.29)	11.1 (± 16.67)	9.1 (± 15.57)	21.2 (± 34.23)
Diarrhoea, CFB to EoT	-13.3 (± 29.81)	-16.7 (± 23.57)	-5.6 (± 13.61)	0.0 (± 30.86)
FD, Baseline (Day 1)	36.1 (± 30.01)	7.4 (± 14.70)	24.2 (± 36.79)	15.2 (± 17.41)
FD, CFB to EoT	-13.3 (± 18.26)	0.0 (± 0.00)	0.0 (± 0.00)	4.2 (± 21.36)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	10	10	8
Units: Score on scale				
arithmetic mean (standard deviation)				
GHS/QoL, Baseline (Day 1)	60.2 (± 26.61)	55.0 (± 24.60)	63.3 (± 16.29)	67.7 (± 15.71)
GHS/QoL, CFB to EoT	-4.2 (± 17.68)	-8.3 (± 9.62)	18.7 (± 23.94)	4.2 (± 20.97)
PF, Baseline (Day 1)	66.7 (± 31.27)	78.7 (± 19.58)	82.0 (± 10.91)	89.4 (± 11.48)
PF, CFB to EoT	3.3 (± 4.71)	-10.0 (± 15.87)	-11.7 (± 42.64)	-1.7 (± 12.62)
RF, Baseline (Day 1)	70.4 (± 33.10)	73.3 (± 19.56)	71.7 (± 22.29)	89.6 (± 19.80)
RF, CFB to EoT	0.0 (± 0.00)	-20.8 (± 34.36)	20.8 (± 36.96)	-4.2 (± 28.46)
EF, Baseline (Day 1)	83.3 (± 13.18)	78.3 (± 17.21)	83.3 (± 16.20)	91.7 (± 8.91)
EF, CFB to EoT	-12.5 (± 5.89)	2.1 (± 14.23)	-12.5 (± 15.96)	6.3 (± 12.50)
CF, Baseline (Day 1)	74.1 (± 16.90)	83.3 (± 22.22)	95.0 (± 8.05)	91.7 (± 12.60)
CF, CFB to EoT	8.3 (± 11.79)	-8.3 (± 21.52)	-16.7 (± 27.22)	-8.3 (± 9.62)
SF, Baseline (Day 1)	72.2 (± 34.36)	68.3 (± 34.65)	73.3 (± 17.92)	75.0 (± 23.57)
SF, CFB to EoT	0.0 (± 0.00)	8.3 (± 16.67)	-12.5 (± 34.36)	16.7 (± 19.25)
Fatigue, Baseline (Day 1)	30.9 (± 30.32)	32.2 (± 23.10)	37.8 (± 25.77)	31.9 (± 3.93)
Fatigue, CFB to EoT	11.1 (± 15.71)	2.8 (± 18.98)	-2.8 (± 41.94)	-11.1 (± 12.83)

N/V, Baseline (Day 1)	5.6 (± 8.33)	8.3 (± 11.79)	5.0 (± 8.05)	2.1 (± 5.89)
N/V, CFB to EoT	0.0 (± 0.00)	-4.2 (± 8.33)	4.2 (± 8.33)	0.0 (± 13.61)
Pain, Baseline (Day 1)	42.6 (± 33.45)	28.3 (± 20.86)	36.7 (± 25.82)	22.9 (± 21.71)
Pain, CFB to EoT	-8.3 (± 11.79)	25.0 (± 31.91)	-4.2 (± 43.83)	8.3 (± 16.67)
Dyspnoea, Baseline (Day 1)	14.8 (± 24.22)	16.7 (± 17.57)	16.7 (± 17.57)	8.3 (± 15.43)
Dyspnoea, CFB to EoT	16.7 (± 23.57)	0.0 (± 0.00)	16.7 (± 19.25)	0.0 (± 0.00)
Insomnia, Baseline (Day 1)	37.0 (± 38.89)	33.3 (± 31.43)	30.0 (± 33.15)	8.3 (± 15.43)
Insomnia, CFB to EoT	0.0 (± 47.14)	-16.7 (± 19.25)	0.0 (± 54.43)	0.0 (± 0.00)
AL, Baseline (Day 1)	22.2 (± 23.57)	26.7 (± 26.29)	6.7 (± 14.05)	12.5 (± 24.80)
AL, CFB to EoT	0.0 (± 0.00)	-8.3 (± 41.94)	25.0 (± 50.00)	-8.3 (± 16.67)
Constipation, Baseline (Day 1)	7.4 (± 22.22)	13.3 (± 17.21)	20.0 (± 32.20)	8.3 (± 15.43)
Constipation, CFB to EoT	0.0 (± 0.00)	0.0 (± 0.00)	-25.0 (± 31.91)	16.7 (± 19.25)
Diarrhoea, Baseline (Day 1)	11.1 (± 33.33)	6.7 (± 21.08)	6.7 (± 14.05)	12.5 (± 17.25)
Diarrhoea, CFB to EoT	0.0 (± 0.00)	0.0 (± 27.22)	16.7 (± 19.25)	-8.3 (± 31.91)
FD, Baseline (Day 1)	25.9 (± 27.78)	26.7 (± 37.84)	20.0 (± 35.83)	20.8 (± 35.36)
FD, CFB to EoT	0.0 (± 0.00)	16.7 (± 19.25)	8.3 (± 16.67)	-16.7 (± 33.33)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in EORTC QLQ 20-item Multiple Myeloma Module (MY20) Score - All treated population

End point title	Change From Baseline in EORTC QLQ 20-item Multiple Myeloma Module (MY20) Score - All treated population

End point description:

The EORTC QLQ-MY20 is a supplement to the QLQ-C30 instrument used in participants with multiple myeloma. The module comprised of 20 questions that addressed four myeloma-specific HRQoL domains: disease symptoms (DS), side effects of treatment (SET), future perspective (FP) and body image (BI). Responses are 1 to 4. Scores were averaged and scales were transformed to 0 to 100 scale. A high score for disease symptoms and side effects of treatment represented a high level of symptomatology or problems, whereas a high score for future perspective and body image represented better outcomes. Baseline (Day 1) was defined as latest pre-dose assessment with non-missing value, including unscheduled visits. Change from Baseline was calculated by subtracting Baseline value from the post-dose visit value.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and up to approximately 4.5 years

End point values	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE +	Belantamab mafodotin 2.5mg/kg SPLIT +	Belantamab mafodotin 2.5mg/kg SINGLE +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	3	10	9
Units: Score on scale				
arithmetic mean (standard deviation)				

DS, Baseline (Day 1)	45.0 (± 25.45)	24.1 (± 22.45)	26.6 (± 12.22)	24.7 (± 19.47)
DS, CFB to EoT	-14.8 (± 17.86)	-8.3 (± 27.50)	10.0 (± 9.34)	-5.6 (± 36.00)
SET, Baseline (Day 1)	27.5 (± 16.65)	21.0 (± 18.64)	19.9 (± 11.20)	18.8 (± 13.87)
SET, CFB to EoT	-11.4 (± 15.19)	-14.8 (± 15.71)	0.1 (± 7.86)	0.0 (± 9.07)
BI, Baseline (Day 1)	83.3 (± 17.57)	100.0 (± 0.00)	76.7 (± 31.62)	81.5 (± 24.22)
BI, CFB to EoT	-11.1 (± 50.92)	-16.7 (± 23.57)	-8.3 (± 31.91)	8.3 (± 41.94)
FP, Baseline (Day 1)	58.9 (± 29.65)	48.1 (± 12.83)	58.9 (± 28.71)	72.8 (± 16.77)
FP, CFB to EoT	-7.4 (± 51.32)	38.9 (± 39.28)	16.7 (± 19.25)	13.9 (± 13.98)

End point values	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	11	9
Units: Score on scale				
arithmetic mean (standard deviation)				
DS, Baseline (Day 1)	40.7 (± 19.58)	21.0 (± 19.40)	21.2 (± 17.88)	31.5 (± 21.15)
DS, CFB to EoT	23.3 (± 26.76)	-2.8 (± 19.64)	-8.3 (± 10.39)	5.6 (± 22.22)
SET, Baseline (Day 1)	23.6 (± 13.79)	7.7 (± 6.87)	12.7 (± 9.65)	15.1 (± 9.43)
SET, CFB to EoT	0.0 (± 14.60)	1.9 (± 7.86)	3.3 (± 5.00)	19.0 (± 19.38)
BI, Baseline (Day 1)	77.8 (± 29.59)	85.2 (± 24.22)	69.7 (± 37.87)	88.9 (± 16.67)
BI, CFB to EoT	6.7 (± 14.91)	0.0 (± 0.00)	0.0 (± 0.00)	-9.5 (± 16.27)
FP, Baseline (Day 1)	65.7 (± 17.38)	67.9 (± 17.07)	55.6 (± 31.03)	59.3 (± 23.57)
FP, CFB to EoT	-6.7 (± 21.66)	0.0 (± 15.71)	1.9 (± 14.77)	-3.2 (± 22.87)

End point values	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	10	10	8
Units: Score on scale				
arithmetic mean (standard deviation)				
DS, Baseline (Day 1)	29.0 (± 23.37)	26.7 (± 15.89)	25.6 (± 20.15)	18.8 (± 8.88)
DS, CFB to EoT	5.6 (± 15.71)	-2.8 (± 18.43)	12.5 (± 20.48)	4.2 (± 13.13)
SET, Baseline (Day 1)	14.9 (± 6.21)	16.7 (± 14.21)	13.9 (± 13.60)	11.3 (± 8.99)
SET, CFB to EoT	1.1 (± 6.81)	-2.7 (± 8.74)	5.6 (± 8.74)	6.5 (± 20.14)
BI, Baseline (Day 1)	77.8 (± 33.33)	90.0 (± 22.50)	93.3 (± 14.05)	75.0 (± 34.50)
BI, CFB to EoT	0.0 (± 0.00)	-8.3 (± 16.67)	-8.3 (± 16.67)	16.7 (± 19.25)
FP, Baseline (Day 1)	58.0 (± 34.15)	62.2 (± 15.00)	63.3 (± 16.60)	66.7 (± 13.28)
FP, CFB to EoT	-5.6 (± 7.86)	-8.3 (± 31.91)	-2.8 (± 44.79)	22.2 (± 15.71)

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 up to approximately 4.5 years.

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	25.1

Reporting groups

Reporting group title	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg dose on Day 1 and a 1.25 mg/kg dose on Day 8 of each 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex

Reporting group description:

Participants with Relapsed or Refractory Multiple Myeloma (RRMM) received belantamab mafodotin as 1.9 milligram (mg)/kilogram (kg) dose on Day 1 of every alternate 28-day cycles (C1, C3, C5, C7 and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg per oral (PO) on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ intravenously (IV) on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 28-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Lenalidomide was administered as 25 mg or 10 mg PO on Days 1-21 of each 28-day cycle with 40 mg Dexamethasone weekly PO/ IV on Days 1, 8, 15 and 22 of each cycle.

Reporting group title	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 2.5mg/kg dose as a 1.25 mg/kg on Day 1 and 1.25 mg/kg dose on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 2.5 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as two equal divided doses of a total 3.4 mg/kg dose as a 1.7 mg/kg dose on Day 1 and 1.7 mg/kg on Day 8 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on

Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on Day 1 of every alternate 21-day cycles (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 2.5 mg/kg dose on cycle 1 day 1 (C1D1) followed by 1.9 mg/kg step-down dose on Day 1 of every alternate 21-day cycles C3 onwards (C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 3.4 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as 1.9 mg/kg dose on Day 1 of every alternate 21-day cycle (C1, C3, C5, C7, and so on) as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 subcutaneously (SC) /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Reporting group title	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex

Reporting group description:

Participants with RRMM received belantamab mafodotin as SINGLE full dose of 1.9 mg/kg on Day 1 of every 21-day cycle as a 30-60 minute infusion. Along with belantamab mafodotin, Bortezomib was administered as 1.3 mg/m^2 SC /IV on Days 1, 4, 8, and 11 with 20 mg Dexamethasone PO/IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of every 21-day cycle up to 8 cycles.

Serious adverse events	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 13 (46.15%)	2 / 4 (50.00%)	6 / 12 (50.00%)
number of deaths (all causes)	6	2	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Bowen’s disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Plasmacytoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Tumour pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Epistaxis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Asthma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Haemothorax			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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

Pulmonary oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Ankle fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Femur fracture			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Contusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Ilium fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Lower limb fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Procedural pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Rib fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Sternal fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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			
Atrial fibrillation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
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 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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 arrest			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Cerebrovascular accident			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autonomic neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Cerebral haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Sciatica			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Encephalopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Syncope			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Neutropenia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Cytopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Iron deficiency anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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

Diarrhoea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Constipation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Faecaloma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Diverticulum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Gastritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Irritable bowel syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Intestinal obstruction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Pancreatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Obstruction gastric			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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			
Urinary retention			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Arthralgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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

Musculoskeletal chest pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Neck pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Bone pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Flank pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Myopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Pathological fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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			
Lower respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences causally related to treatment / all	3 / 5	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Meningitis cryptococcal			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Gastroenteritis norovirus			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Septic shock			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Urosepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Influenza			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Campylobacter infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Abscess limb			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Device related infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Coronavirus infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Gastrointestinal infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Respiratory tract infection viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Rhinovirus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Metabolism and nutrition disorders			
Hypomagnesaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Dehydration			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Hypercalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (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

Serious adverse events	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 16 (62.50%)	7 / 13 (53.85%)	13 / 18 (72.22%)
number of deaths (all causes)	8	5	8
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Malignant melanoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Bowen’s disease			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Plasmacytoma			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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

Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Haemothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Pulmonary oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
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			
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Femur fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Contusion			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Ilium fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Rib fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Sternal fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
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 disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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 failure congestive			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Atrioventricular block second degree			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Atrial flutter			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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 arrest			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Supraventricular tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Myocardial infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Autonomic neuropathy			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Sciatica			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
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			
Anaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Haemorrhoids			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Incarcerated inguinal hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Faecaloma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Irritable bowel syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Obstruction gastric			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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			
Urinary retention			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Arthralgia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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

Neck pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Bone pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Myopathy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Lower respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 16 (18.75%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	1 / 5	0 / 1	2 / 5
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
COVID-19			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Campylobacter colitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Meningitis cryptococcal			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Gastroenteritis norovirus			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Sepsis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Streptococcal sepsis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	2 / 13 (15.38%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 16 (0.00%)	2 / 13 (15.38%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Abscess limb			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Coronavirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Rhinovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Metabolism and nutrition disorders			
Hypomagnesaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (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
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 12 (50.00%)	6 / 12 (50.00%)	6 / 12 (50.00%)
number of deaths (all causes)	6	5	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen’s disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Plasmacytoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Tumour pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Haemothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Pulmonary oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Psychiatric disorders			
Anxiety			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
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			
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Ankle fracture			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Femur fracture			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ilium fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Lower limb fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Sternal fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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 failure congestive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Atrioventricular block second degree			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
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 arrest			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Supraventricular tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Autonomic neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Encephalopathy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Thrombocytopenia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Faecaloma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Diverticulum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Irritable bowel syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pancreatitis			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Flank pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Myopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pathological fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cellulitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Meningitis cryptococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastroenteritis norovirus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pneumocystis jirovecii pneumonia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pseudomonas infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Sepsis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Streptococcal sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Urosepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Influenza			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Bacteraemia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Campylobacter infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Staphylococcal bacteraemia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (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
Abscess limb			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Coronavirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastrointestinal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Lower respiratory tract infection viral			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Respiratory tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Rhinovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Metabolism and nutrition disorders			
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Tumour lysis syndrome			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Serious adverse events	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 16 (56.25%)	8 / 12 (66.67%)	8 / 12 (66.67%)
number of deaths (all causes)	4	4	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Bowen’s disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmacytoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Tumour pain			

subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (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
Squamous cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pulmonary oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Investigations			

Platelet count decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Fall			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Femur fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Contusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Ilium fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Lower limb fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Procedural pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Rib fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Sternal fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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 failure congestive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Atrioventricular block second degree			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
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 arrest			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Autonomic neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cerebral haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Encephalopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Febrile neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Haemorrhoids			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Diarrhoea			
subjects affected / exposed	1 / 16 (6.25%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Constipation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Diverticulum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (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 haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pancreatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Obstruction gastric			

subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (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
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Arthralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Neck pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Flank pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Myopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pathological fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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			
Lower respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 16 (6.25%)	3 / 12 (25.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
COVID-19			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Meningitis cryptococcal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastroenteritis norovirus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Urosepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Influenza			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			

subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Abscess limb			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Coronavirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Gastrointestinal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Respiratory tract infection viral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (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
Rhinovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Metabolism and nutrition disorders			
Hypomagnesaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Dehydration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

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

Non-serious adverse events	Belantamab mafodotin 2.5mg/kg SPLIT + Len/Dex	Belantamab mafodotin 1.9mg/kg SINGLE + Len/Dex	Belantamab mafodotin 1.9mg/kg STRETCH + Len/Dex
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	4 / 4 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lentigo maligna			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuroendocrine tumour			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin cancer			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Plasmacytoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vascular disorders			
Embolism venous			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Phlebitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site bruise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Catheter site pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Crepitations			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 13 (30.77%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	5	0	0
Feeling abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Gait disturbance			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Injection site bruising			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Soft tissue inflammation			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Testicular pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital lesion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Testicular swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Cough			

subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	3 / 12 (25.00%)
occurrences (all)	1	2	3
Atelectasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Nasal congestion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Nasal ulcer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pleuritic pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Wheezing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Agitation			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Delirium			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 13 (7.69%)	2 / 4 (50.00%)	5 / 12 (41.67%)
occurrences (all)	2	4	6

Irritability			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			

subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Blood creatinine increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood uric acid decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Grip strength decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Intraocular pressure increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipids increased			

subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	5 / 13 (38.46%)	1 / 4 (25.00%)	3 / 12 (25.00%)
occurrences (all)	7	1	3
Occult blood positive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	4 / 13 (30.77%)	1 / 4 (25.00%)	4 / 12 (33.33%)
occurrences (all)	9	2	5
Liver function test abnormal			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual acuity tests abnormal			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Urine output decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Staphylococcus test positive			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

White blood cell count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chemical burns of eye			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Corneal abrasion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Joint dislocation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Skin abrasion			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Periorbital haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Muir-Torre syndrome			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Aortic valve disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Atrial flutter			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block first degree			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic dysfunction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Atrioventricular block second degree			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mitral valve disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pericardial effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Palpitations			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ventricular hypokinesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ageusia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphasia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Autonomic neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	4 / 12 (33.33%)
occurrences (all)	0	0	6
Dysaesthesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Hypoaesthesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lethargy			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Migraine			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Presyncope			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Sensory loss			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Somnolence			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	4 / 13 (30.77%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	5	0	2
Lymphopenia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Iron deficiency anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	3 / 13 (23.08%)	2 / 4 (50.00%)	0 / 12 (0.00%)
occurrences (all)	18	3	0
Neutrophilia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	8	1	1
Ear and labyrinth disorders			
Deafness unilateral			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Tinnitus			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenopia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blepharitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Blepharospasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Blindness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blindness unilateral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	8
Cataract cortical			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	4
Cataract			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Chalazion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cornea verticillata			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Corneal opacity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Corneal oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Erythema of eyelid			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	0	2	4
Eye irritation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Eye pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Foreign body sensation in eyes			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	6	0	3
Eye pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night blindness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Meibomian gland dysfunction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Lacrimation increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Keratopathy			
subjects affected / exposed	12 / 13 (92.31%)	3 / 4 (75.00%)	9 / 12 (75.00%)
occurrences (all)	122	52	114
Ocular hyperaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Posterior capsule opacification			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Retinal vein occlusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	7 / 13 (53.85%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	12	2	0
Uveitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	4 / 13 (30.77%)	1 / 4 (25.00%)	5 / 12 (41.67%)
occurrences (all)	29	23	26
Vitreous haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 13 (7.69%)	2 / 4 (50.00%)	2 / 12 (16.67%)
occurrences (all)	1	2	2
Abdominal pain upper			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Aerophagia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Colitis microscopic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Anal incontinence			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	3 / 13 (23.08%)	2 / 4 (50.00%)	2 / 12 (16.67%)
occurrences (all)	3	2	3
Diverticulum intestinal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	6 / 13 (46.15%)	3 / 4 (75.00%)	5 / 12 (41.67%)
occurrences (all)	9	6	9
Diverticulum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Dysphagia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Gastritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Gingival bleeding			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gingival swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Hypoaesthesia oral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Irritable bowel syndrome			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Loose tooth			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 13 (30.77%)	2 / 4 (50.00%)	2 / 12 (16.67%)
occurrences (all)	5	2	2
Tooth loss			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blood blister			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cold urticaria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Petechiae			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	1	2	3
Purpura			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Skin disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin plaque			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Chronic kidney disease			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhage urinary tract			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Urinary hesitation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urinary tract pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 13 (23.08%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Back pain			
subjects affected / exposed	3 / 13 (23.08%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	3	1	2
Arthritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Bone cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest wall haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Costochondritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Exposed bone in jaw			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diffuse idiopathic skeletal hyperostosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Kyphosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Muscle atrophy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	4	0	2
Muscular weakness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Musculoskeletal chest pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 4 (25.00%)	1 / 12 (8.33%)
occurrences (all)	1	2	1

Neck pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Pain in extremity			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	2 / 12 (16.67%)
occurrences (all)	3	0	2
Spondyloarthropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	3 / 12 (25.00%)
occurrences (all)	2	0	3
Bronchitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Campylobacter colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Campylobacter infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Device related infection			

subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Epididymitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Helicobacter gastritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Gastrointestinal infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 13 (0.00%)	1 / 4 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nosocomial infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Parainfluenzae virus infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Picornavirus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Prostate infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Sepsis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 13 (15.38%)	1 / 4 (25.00%)	2 / 12 (16.67%)
occurrences (all)	4	1	2
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	4 / 12 (33.33%)
occurrences (all)	0	0	8
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Varicella zoster virus infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urinary tract infection viral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Appetite disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Hypoalbuminaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Hypoglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Magnesium deficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Steroid diabetes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 4 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Belantamab mafodotin 2.5mg/kg SINGLE + Len/Dex	Belantamab mafodotin 2.5 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg SINGLE + Bor/Dex
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	13 / 13 (100.00%)	18 / 18 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Lentigo maligna			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Malignant melanoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neuroendocrine tumour			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin cancer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Plasmacytoma			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism venous			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Flushing			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Orthostatic hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Hot flush			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	4 / 18 (22.22%)
occurrences (all)	3	0	5
Phlebitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Catheter site bruise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	3 / 16 (18.75%)	2 / 13 (15.38%)	0 / 18 (0.00%)
occurrences (all)	5	3	0
Catheter site pain			

subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Chills			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	6
Crepitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Face oedema			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Facial pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	7 / 16 (43.75%)	4 / 13 (30.77%)	6 / 18 (33.33%)
occurrences (all)	10	5	6
Feeling abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Injection site bruising			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	2 / 16 (12.50%)	2 / 13 (15.38%)	3 / 18 (16.67%)
occurrences (all)	6	2	5
Oedema			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 16 (18.75%)	2 / 13 (15.38%)	2 / 18 (11.11%)
occurrences (all)	3	2	2
Soft tissue inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Swelling			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Genital lesion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	4 / 16 (25.00%)	2 / 13 (15.38%)	2 / 18 (11.11%)
occurrences (all)	4	2	2
Cough			
subjects affected / exposed	2 / 16 (12.50%)	4 / 13 (30.77%)	3 / 18 (16.67%)
occurrences (all)	3	4	4
Atelectasis			

subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	1 / 16 (6.25%)	3 / 13 (23.08%)	2 / 18 (11.11%)
occurrences (all)	1	3	3
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	5
Nasal ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pneumothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	4
Throat irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Agitation			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	1	1	2
Delirium			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Insomnia			
subjects affected / exposed	6 / 16 (37.50%)	3 / 13 (23.08%)	6 / 18 (33.33%)
occurrences (all)	7	3	6
Irritability			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	1

Mental status changes			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Mood altered			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 16 (25.00%)	2 / 13 (15.38%)	1 / 18 (5.56%)
occurrences (all)	6	2	1
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 16 (12.50%)	2 / 13 (15.38%)	2 / 18 (11.11%)
occurrences (all)	2	2	2
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 13 (15.38%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Blood creatinine increased			

subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Blood uric acid decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Grip strength decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 16 (18.75%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	4	1	0
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Intraocular pressure increased			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Lipids increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	4 / 16 (25.00%)	1 / 13 (7.69%)	9 / 18 (50.00%)
occurrences (all)	6	1	11
Occult blood positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	5 / 16 (31.25%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	14	2	5
Liver function test abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Visual acuity tests abnormal			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	0	1	25
Urine output decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Troponin T increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	1	1	2
Staphylococcus test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Weight increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	3
White blood cells urine positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Chemical burns of eye			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	3 / 16 (18.75%)	1 / 13 (7.69%)	4 / 18 (22.22%)
occurrences (all)	5	2	5
Corneal abrasion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	3 / 16 (18.75%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	3	1	2
Infusion related reaction			
subjects affected / exposed	3 / 16 (18.75%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Joint dislocation			

subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tendon rupture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Periorbital haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Wrist fracture			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Muir-Torre syndrome			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			

Aortic valve disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block first degree			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Diastolic dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block second degree			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Mitral valve disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1

Sinus bradycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Sinus tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ventricular hypokinesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ageusia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Anosmia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Aphasia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Balance disorder			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Autonomic neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Burning sensation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cognitive disorder			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	2	1	4
Dysaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Headache			
subjects affected / exposed	5 / 16 (31.25%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	5	1	2
Hypoaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Lethargy			
subjects affected / exposed	1 / 16 (6.25%)	2 / 13 (15.38%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Migraine			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	1	1	2
Peripheral motor neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Neuropathy peripheral			
subjects affected / exposed	3 / 16 (18.75%)	3 / 13 (23.08%)	6 / 18 (33.33%)
occurrences (all)	3	5	8
Restless legs syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 16 (18.75%)	1 / 13 (7.69%)	4 / 18 (22.22%)
occurrences (all)	3	1	6
Presyncope			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Radiculopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sensory loss			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	5 / 16 (31.25%)	3 / 13 (23.08%)	4 / 18 (22.22%)
occurrences (all)	5	3	5
Lymphopenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	2 / 16 (12.50%)	2 / 13 (15.38%)	2 / 18 (11.11%)
occurrences (all)	3	3	10
Neutrophilia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	7 / 16 (43.75%)	9 / 13 (69.23%)	6 / 18 (33.33%)
occurrences (all)	7	13	18
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypoacusis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
External ear pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Middle ear effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Asthenopia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Blepharitis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	2	3	8
Blepharospasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blindness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Blindness unilateral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cataract subcapsular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	4
Cataract nuclear			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Cataract cortical			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	5
Cataract			
subjects affected / exposed	3 / 16 (18.75%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
Chalazion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	0	2	3
Conjunctival hyperaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Conjunctivitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cornea verticillata			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Corneal opacity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2

Corneal oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Erythema of eyelid			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	4 / 18 (22.22%)
occurrences (all)	2	2	9
Eye irritation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Eye pain			
subjects affected / exposed	2 / 16 (12.50%)	3 / 13 (23.08%)	4 / 18 (22.22%)
occurrences (all)	6	4	10
Foreign body sensation in eyes			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	2	2	1
Eye pruritus			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	2	2	0
Glaucoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Keratitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Night blindness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	3
Meibomian gland dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	0	2	5

Lacrimation increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Keratopathy			
subjects affected / exposed	11 / 16 (68.75%)	10 / 13 (76.92%)	15 / 18 (83.33%)
occurrences (all)	224	97	188
Ocular hyperaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Ocular discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 16 (0.00%)	4 / 13 (30.77%)	6 / 18 (33.33%)
occurrences (all)	0	9	12
Posterior capsule opacification			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	6
Retinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Retinal vein occlusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1

Vision blurred			
subjects affected / exposed	6 / 16 (37.50%)	5 / 13 (38.46%)	12 / 18 (66.67%)
occurrences (all)	27	17	56
Uveitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Visual acuity reduced			
subjects affected / exposed	5 / 16 (31.25%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	77	2	2
Vitreous haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vitreous detachment			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	4
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 16 (6.25%)	2 / 13 (15.38%)	0 / 18 (0.00%)
occurrences (all)	1	5	0
Abdominal pain upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Aerophagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Colitis microscopic			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Anal fistula			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 16 (18.75%)	2 / 13 (15.38%)	6 / 18 (33.33%)
occurrences (all)	3	4	6
Diverticulum intestinal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Dental caries			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	6 / 16 (37.50%)	4 / 13 (30.77%)	8 / 18 (44.44%)
occurrences (all)	11	6	12
Diverticulum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	3 / 18 (16.67%)
occurrences (all)	1	0	4
Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	3
Flatulence			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 16 (0.00%)	2 / 13 (15.38%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Gingival bleeding			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Haemorrhoids			

subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Loose tooth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Oral pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 16 (18.75%)	3 / 13 (23.08%)	8 / 18 (44.44%)
occurrences (all)	4	5	18
Tooth loss			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	3
Rectal haemorrhage			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Proctalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	3 / 16 (18.75%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 16 (12.50%)	2 / 13 (15.38%)	3 / 18 (16.67%)
occurrences (all)	2	4	4
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Actinic keratosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blister			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Cold urticaria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Photosensitivity reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Rash maculo-papular			
subjects affected / exposed	2 / 16 (12.50%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	3	1	3
Skin disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0

Chronic kidney disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Haemorrhage urinary tract			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	2
Urinary hesitation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Urinary incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Urinary tract pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Endocrine disorders			
Thyroid mass			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 16 (18.75%)	4 / 13 (30.77%)	3 / 18 (16.67%)
occurrences (all)	5	5	3
Back pain			
subjects affected / exposed	1 / 16 (6.25%)	3 / 13 (23.08%)	5 / 18 (27.78%)
occurrences (all)	1	3	5
Arthritis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1
Bone cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Chest wall haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	2	0	2
Bone pain			
subjects affected / exposed	2 / 16 (12.50%)	3 / 13 (23.08%)	1 / 18 (5.56%)
occurrences (all)	2	3	1
Costochondritis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Exposed bone in jaw			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Diffuse idiopathic skeletal hyperostosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	2
Limb discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Kyphosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	4 / 16 (25.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	8	0	0
Muscular weakness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Musculoskeletal chest pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	3 / 16 (18.75%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0

Neck pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Osteoarthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Osteonecrosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Osteonecrosis of jaw			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	2 / 16 (12.50%)	3 / 13 (23.08%)	2 / 18 (11.11%)
occurrences (all)	2	3	2
Spondyloarthropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	3
Tendon pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Bacterial disease carrier			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	3 / 16 (18.75%)	2 / 13 (15.38%)	0 / 18 (0.00%)
occurrences (all)	3	3	0
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Campylobacter colitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Candida infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Campylobacter infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	3
Conjunctivitis bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Device related infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Escherichia urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Eye infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Helicobacter gastritis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Herpes ophthalmic			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Gastrointestinal infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Lower respiratory tract infection			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	2	0	4
Lip infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Kidney infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Nosocomial infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Parainfluenzae virus infection			

subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Picornavirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Prostate infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Rhinovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Sepsis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tinea pedis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Streptococcal bacteraemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 16 (18.75%)	2 / 13 (15.38%)	9 / 18 (50.00%)
occurrences (all)	4	2	11
Urinary tract infection			
subjects affected / exposed	2 / 16 (12.50%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	2	1	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Varicella zoster virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Decreased appetite			
subjects affected / exposed	3 / 16 (18.75%)	0 / 13 (0.00%)	5 / 18 (27.78%)
occurrences (all)	3	0	7
Appetite disorder			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Folate deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Fluid retention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0

Hypoalbuminaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 13 (15.38%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Hypocalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	4 / 16 (25.00%)	1 / 13 (7.69%)	3 / 18 (16.67%)
occurrences (all)	4	1	3
Hypomagnesaemia			
subjects affected / exposed	4 / 16 (25.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	4	1	0
Hyponatraemia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 13 (7.69%)	2 / 18 (11.11%)
occurrences (all)	4	1	4
Hypophosphataemia			
subjects affected / exposed	1 / 16 (6.25%)	2 / 13 (15.38%)	0 / 18 (0.00%)
occurrences (all)	1	6	0
Magnesium deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Steroid diabetes			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Belantamab mafodotin 3.4 mg/kg SPLIT + Bor/Dex	Belantamab mafodotin 2.5 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 2.5 mg/kg Step-Down STRETCH+ Bor/Dex
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	12 / 12 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lentigo maligna			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Neuroendocrine tumour			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Plasmacytoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vascular disorders			
Embolism venous			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 12 (16.67%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	2	2	2
Phlebitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site bruise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Crepitations			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Disease progression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 12 (41.67%)	5 / 12 (41.67%)	4 / 12 (33.33%)
occurrences (all)	5	5	5
Feeling abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site bruising			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	5 / 12 (41.67%)	4 / 12 (33.33%)
occurrences (all)	0	5	5
Oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	2	0	2
Soft tissue inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 12 (25.00%)	3 / 12 (25.00%)	0 / 12 (0.00%)
occurrences (all)	3	3	0
Cough			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Atelectasis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	0 / 12 (0.00%)
occurrences (all)	1	3	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Nasal ulcer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Throat irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Delirium			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 12 (8.33%)	4 / 12 (33.33%)	3 / 12 (25.00%)
occurrences (all)	1	4	3
Irritability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Mental status changes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Persistent depressive disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	2 / 12 (16.67%)
occurrences (all)	1	5	2
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	4 / 12 (33.33%)	5 / 12 (41.67%)
occurrences (all)	1	6	5
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	0	1	3
Blood creatinine increased			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood uric acid decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Grip strength decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	6 / 12 (50.00%)	1 / 12 (8.33%)
occurrences (all)	1	6	1
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Intraocular pressure increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Lipids increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	3 / 12 (25.00%)	7 / 12 (58.33%)	7 / 12 (58.33%)
occurrences (all)	3	12	12
Occult blood positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	0	2	4
Liver function test abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	5 / 12 (41.67%)
occurrences (all)	0	1	5
Visual acuity tests abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Troponin T increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Staphylococcus test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Weight increased			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
White blood cells urine positive			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Bone contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chemical burns of eye			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Corneal abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Eye injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Infusion related reaction			
subjects affected / exposed	3 / 12 (25.00%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	4	2	1
Joint dislocation			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toxicity to various agents			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Muir-Torre syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Aortic valve disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Atrial flutter			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mitral valve disease			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Mitral valve incompetence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0

Sinus bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ventricular hypokinesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ageusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Balance disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Autonomic neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	1 / 12 (8.33%)
occurrences (all)	2	3	1
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 12 (8.33%)	4 / 12 (33.33%)	1 / 12 (8.33%)
occurrences (all)	1	4	2
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Migraine			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	3 / 12 (25.00%)	3 / 12 (25.00%)	2 / 12 (16.67%)
occurrences (all)	5	5	2
Restless legs syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 12 (16.67%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	3	2	2
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Syncope			

subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	2 / 12 (16.67%)	3 / 12 (25.00%)	2 / 12 (16.67%)
occurrences (all)	2	3	2
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Neutrophilia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	9 / 12 (75.00%)	5 / 12 (41.67%)	3 / 12 (25.00%)
occurrences (all)	10	9	10
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Blepharitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Blepharospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blindness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Blindness unilateral			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cataract subcapsular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cataract nuclear			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Cataract cortical			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Chalazion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Conjunctival hyperaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Cornea verticillata			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Corneal opacity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Corneal oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema of eyelid			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 12 (0.00%)	3 / 12 (25.00%)	0 / 12 (0.00%)
occurrences (all)	0	5	0
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Eye pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Eye pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night blindness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Keratopathy			
subjects affected / exposed	10 / 12 (83.33%)	12 / 12 (100.00%)	12 / 12 (100.00%)
occurrences (all)	130	85	123
Ocular hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Periorbital oedema			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Periorbital swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Posterior capsule opacification			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Punctate keratitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retinal vein occlusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Vision blurred			
subjects affected / exposed	3 / 12 (25.00%)	5 / 12 (41.67%)	5 / 12 (41.67%)
occurrences (all)	6	9	10
Uveitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	2 / 12 (16.67%)	4 / 12 (33.33%)	4 / 12 (33.33%)
occurrences (all)	39	24	49
Vitreous haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vitreous detachment			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Visual impairment			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Abdominal pain			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	3 / 12 (25.00%)
occurrences (all)	3	0	3
Abdominal pain upper			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Aerophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Colitis microscopic			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	5 / 12 (41.67%)
occurrences (all)	0	2	7
Diverticulum intestinal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dental caries			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	6 / 12 (50.00%)
occurrences (all)	1	0	11
Diverticulum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Lip swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oral discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	5 / 12 (41.67%)
occurrences (all)	2	1	5
Tooth loss			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Stomatitis			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blister			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cold urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	5	0	2
Purpura			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Skin disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin plaque			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Chronic kidney disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Haemorrhage urinary tract			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Urinary hesitation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Thyroid mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	3 / 12 (25.00%)
occurrences (all)	0	2	3
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest wall haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
Costochondritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Exposed bone in jaw			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diffuse idiopathic skeletal hyperostosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Kyphosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Muscular weakness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2

Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Spondyloarthropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tendon disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	4 / 12 (33.33%)
occurrences (all)	1	0	4
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Campylobacter colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Campylobacter infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Device related infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Enterovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Epididymitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Helicobacter gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Lip infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Nosocomial infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Parainfluenzae virus infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Picornavirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Prostate infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sepsis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	4	0	2
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Varicella zoster virus infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Appetite disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Hypoalbuminaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Magnesium deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Steroid diabetes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Belantamab mafodotin 3.4 mg/kg SINGLE + Bor/Dex	Belantamab mafodotin 1.9 mg/kg STRETCH + Bor/Dex	Belantamab mafodotin 1.9 mg/kg SINGLE + Bor/Dex
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	12 / 12 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoma benign			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lentigo maligna			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuroendocrine tumour			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin cancer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Plasmacytoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism venous			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Deep vein thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Hot flush			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	2	1	2
Phlebitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter site bruise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Crepitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Disease progression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Facial pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 16 (18.75%)	3 / 12 (25.00%)	5 / 12 (41.67%)
occurrences (all)	3	3	6
Feeling abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site bruising			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			

subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	3
Injection site reaction			
subjects affected / exposed	0 / 16 (0.00%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	0	2	2
Mucosal inflammation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	5 / 16 (31.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	5	0	2
Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	3 / 16 (18.75%)	0 / 12 (0.00%)	3 / 12 (25.00%)
occurrences (all)	3	0	4
Soft tissue inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Swelling			

subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Testicular pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Pelvic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital lesion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	4 / 12 (33.33%)
occurrences (all)	2	0	5
Cough			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	0	1	3
Atelectasis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Hypoxia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 16 (6.25%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	1	3	0
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nasal ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Delirium			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	4 / 16 (25.00%)	2 / 12 (16.67%)	6 / 12 (50.00%)
occurrences (all)	4	2	6
Irritability			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Mental status changes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nightmare			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 16 (18.75%)	1 / 12 (8.33%)	3 / 12 (25.00%)
occurrences (all)	3	1	5
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 16 (12.50%)	2 / 12 (16.67%)	3 / 12 (25.00%)
occurrences (all)	2	2	7
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	3
Blood bilirubin increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood cholesterol increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			

subjects affected / exposed	3 / 16 (18.75%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	4
Blood uric acid decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Ejection fraction decreased			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Grip strength decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 16 (12.50%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	2	2	2
Electrocardiogram T wave abnormal			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Intraocular pressure increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Lipids increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	5 / 16 (31.25%)	6 / 12 (50.00%)	9 / 12 (75.00%)
occurrences (all)	7	13	12
Occult blood positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 16 (6.25%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	4	17	2
Liver function test abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Visual acuity tests abnormal			
subjects affected / exposed	3 / 16 (18.75%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	13	0	0
Urine output decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Troponin T increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Staphylococcus test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Weight increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
White blood cells urine positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Chemical burns of eye			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Corneal abrasion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
Joint dislocation			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Overdose			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tooth fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital haematoma			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Toxicity to various agents			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Muir-Torre syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Aortic valve disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Atrial flutter			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Atrioventricular block first degree			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Extrasystoles			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cardiac failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mitral valve disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Sinus bradycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tricuspid valve incompetence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ventricular hypokinesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ageusia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Balance disorder			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Autonomic neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Dysaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 16 (18.75%)	3 / 12 (25.00%)	2 / 12 (16.67%)
occurrences (all)	3	3	2
Hypoaesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Migraine			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	8 / 16 (50.00%)	1 / 12 (8.33%)	3 / 12 (25.00%)
occurrences (all)	10	1	3
Restless legs syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	4 / 16 (25.00%)	2 / 12 (16.67%)	4 / 12 (33.33%)
occurrences (all)	5	2	4
Presyncope			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Radiculopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory loss			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Anaemia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	3 / 12 (25.00%)
occurrences (all)	2	1	6
Lymphopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Iron deficiency anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	7
Neutrophilia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	9 / 16 (56.25%)	4 / 12 (33.33%)	5 / 12 (41.67%)
occurrences (all)	12	8	6
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ear haemorrhage			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenopia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	6	0	1
Blepharospasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blindness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Blindness unilateral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cataract subcapsular			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cataract nuclear			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Cataract cortical			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	1 / 16 (6.25%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	1	4	4
Chalazion			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Conjunctival hyperaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cornea verticillata			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Corneal opacity			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Corneal oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Erythema of eyelid			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	4 / 16 (25.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	7	0	2
Eye irritation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Eye pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	4	0	3
Foreign body sensation in eyes			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Eye pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Glaucoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Keratitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Night blindness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	6	0	2

Lacrimation increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Keratopathy			
subjects affected / exposed	15 / 16 (93.75%)	9 / 12 (75.00%)	11 / 12 (91.67%)
occurrences (all)	143	61	111
Ocular hyperaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Photophobia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Posterior capsule opacification			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Pterygium			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Punctate keratitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retinal vein occlusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Vision blurred			
subjects affected / exposed	7 / 16 (43.75%)	1 / 12 (8.33%)	3 / 12 (25.00%)
occurrences (all)	24	2	7
Uveitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	3 / 16 (18.75%)	4 / 12 (33.33%)	6 / 12 (50.00%)
occurrences (all)	7	26	39
Vitreous haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	2
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	2
Abdominal pain upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Aerophagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Colitis microscopic			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Anal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	7 / 16 (43.75%)	3 / 12 (25.00%)	8 / 12 (66.67%)
occurrences (all)	8	3	8
Diverticulum intestinal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Dental caries			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	4 / 16 (25.00%)	6 / 12 (50.00%)	5 / 12 (41.67%)
occurrences (all)	9	13	6
Diverticulum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 16 (18.75%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	3	2	1
Gingival bleeding			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Inguinal hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Irritable bowel syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Large intestine polyp			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oral discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	7 / 16 (43.75%)	4 / 12 (33.33%)	2 / 12 (16.67%)
occurrences (all)	10	4	2
Tooth loss			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 16 (31.25%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	5	2	2
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypertransaminasaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Actinic keratosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blister			

subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood blister			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Cold sweat			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cold urticaria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Rash			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
Purpura			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Rash maculo-papular			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Skin disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin mass			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0

Chronic kidney disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haemorrhage urinary tract			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Incontinence			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Pollakiuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Urinary hesitation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 16 (0.00%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Urinary tract pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Thyroid mass			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	2	2	1
Back pain			
subjects affected / exposed	3 / 16 (18.75%)	2 / 12 (16.67%)	2 / 12 (16.67%)
occurrences (all)	3	3	2
Arthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest wall haematoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	2 / 16 (12.50%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Costochondritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Exposed bone in jaw			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diffuse idiopathic skeletal hyperostosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Kyphosis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1

Neck pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Spondyloarthropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Infections and infestations			
Abscess			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	3
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Campylobacter colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Campylobacter infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Device related infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Eye infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Helicobacter gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	2
Lower respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Lip infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nosocomial infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae virus infection			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Picornavirus infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pneumonia viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Prostate infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinovirus infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Sepsis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	6 / 16 (37.50%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	6	1	2
Urinary tract infection			
subjects affected / exposed	2 / 16 (12.50%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	3	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Varicella zoster virus infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	3 / 12 (25.00%)
occurrences (all)	3	1	3
Appetite disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Glucose tolerance impaired			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Hypoalbuminaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	3	1	4
Hypomagnesaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	4 / 16 (25.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	6	0	1
Hypophosphataemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
Magnesium deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Steroid diabetes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 May 2018	Protocol Amendment 1 include following: • additional authors who contributed to protocol amendment were added • change in the Primary Medical Monitor • Changes made in the Schedule of Activities tables. The SOA tables have been modified to reflect that the disease assessments need to be performed at regular intervals instead of being linked to the administration of study drugs. Revisions have also been made in the timings and frequency of some assessments. • Minor correction made in the participants' eligibility criteria; participants with prior allogenic SCT will now be excluded (Section 6). • Clarification made on dose delays of study drugs by giving examples of different scenarios (Section 7.2). • All routine and disease evaluation related blood and urine tests now will be done locally; centrally only if unable to perform locally (Table 16) • Administrative changes made throughout the document.
26 April 2019	Protocol Amendment 3 included following changes: i) Protocol was amended to change ECOG eligibility criteria in Arm A from 0-2 to 0-1 ii) to include additional guidance for management of neutropenia / prophylaxis of infections to be implemented across the study on resuming Arm A and iii) more stringent hematological monitoring for both Arm A and Arm B. Administration of belantamab mafodotin divided as two equal administrations a week apart will also be evaluated to see if this dosing schedule would result in improvement of benefit/risk due to ~25% reduction in the maximum concentration while maintaining similar exposure over a cycle compared to the full administration on Day 1. Protocol Amendment 2 also incorporates the Protocol Clarification letter previously issued to study sites, that provided updated guidance on grading corneal events and dosing participants with belantamab mafodotin. Administrative corrections and general program updates are also included in Amendment 2.
13 July 2020	Protocol Amendment 3 included following changes: i) Updated duration of contraception for female participants to align with this guidance of child bearing potential based on review of guidelines on aneugens. ii) Changes to ophthalmologic assessments based on these findings. iii) Reduced dose levels and extended dosing schedules for belantamab mafodotin will be evaluated in Amendment 3. • Arm A (Belantamab mafodotin + Len/Dex; 28-day cycle): A potential extended dosing schedule has been introduced via this amendment, where belantamab mafodotin at 1.9 mg/kg will be administered once every 8 weeks (STRETCH) and will be evaluated dependent on emerging data. The cycle duration will remain 28 days/4 weeks. Up to 12 participants will be enrolled in this new cohort. • Arm B (Belantamab mafodotin + Bor/Dex; 21-day cycle): 4 new dosing cohorts (2.5 mg/kg STRETCH, 2.5 1.9 mg/kg S/D STRETCH, 1.9 mg/kg SINGLE (Q3W dosing) and 1.9 mg/kg STRETCH) are being added. Up to 12 participants will be enrolled in each of these 4 new cohorts.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported