Clinical trial results:
First-in-human, Open-label, Dose-escalation Trial With Expansion Cohorts to Evaluate Safety of Axl-specific Antibody-drug Conjugate (Enapotamab Vedotin, HuMax®-AXL-ADC) in Patients With Solid Tumors

Summary

EudraCT number	2016-002243-42
Trial protocol	DK
Global end of trial date	12 November 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	GCT1021-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02988817
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Genmab A/S
Sponsor organisation address	Kalvebod Brygge 43, Copenhagen V, Denmark, 1560
Public contact	Clinical Trial Information, Genmab A/S, +45 7020 2728, clinicaltrials@genmab.com
Scientific contact	Clinical Trial Information, Genmab A/S, +45 7020 2728, clinicaltrials@genmab.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 February 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to determine the maximum tolerated dose (MTD) and to establish the safety profile of enapotamab vedotin in a mixed population of participants with specified solid tumors.

Protection of trial subjects:

The trial was conducted in accordance with the protocol and amendments, the International Council for Harmonisation E6 guideline for Good Clinical Practice, applicable local regulations, and ethical principles that have their origins in the Declaration of Helsinki. In addition, the trial was conducted in accordance with FDA 21 Code of Federal Regulations parts 312, 50, and 56, and the directive 2001/20/EC of the European Parliament.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 November 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 29
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	United Kingdom: 69
Country: Number of subjects enrolled	Belgium: 48
Country: Number of subjects enrolled	Denmark: 30
Country: Number of subjects enrolled	United States: 127
Worldwide total number of subjects	306
EEA total number of subjects	110

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)	180
From 65 to 84 years	126
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted in 6 countries (Belgium, Denmark, Spain, the United Kingdom, Netherlands, and the United States).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.3 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 0.3 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 0.6 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental

Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 1.0 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.5 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 1.5 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.0 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.0 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.2 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.4 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental

Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.4 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 3Q4W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 0.6 mg/kg was administered intravenously every week for 3 weeks followed by 1 week without dosing over a 28-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.8 mg/kg 3Q4W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 0.8 mg/kg was administered intravenously every week for 3 weeks followed by 1 week without dosing over a 28-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 1.0 mg/kg was administered intravenously every week for 3 weeks followed by 1 week without dosing over a 28-day treatment cycle.

Arm title	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W

Arm description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.2 mg/kg 3Q4W until the end of treatment.

Arm type	Experimental

Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 1.2 mg/kg was administered intravenously every week for 3 weeks followed by 1 week without dosing over a 28-day treatment cycle.

Arm title	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Arm description:

Participants with advanced and/or metastatic NSCLC with classical sensitizing epidermal growth factor receptor (EGFR) mutations and/or EGFR mutations targeted by third-generation tyrosine kinase inhibitors, received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.2 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Arm description:

Participants with advanced and/or metastatic melanoma with BRAF V600 mutation received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.2 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Arm description:

Participants with advanced and/or metastatic melanoma with BRAF V600 wild type received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.2 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Arm description:

Participants with advanced and/or metastatic sarcoma received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.2 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Arm description:

Participants with advanced and/or metastatic solid tumors (excluding NSCLC, melanoma, sarcoma, and ovarian cancer unless having a known AXL gene amplification) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 1.0 mg/kg was administered intravenously every week for 3 weeks followed by 1 week without dosing over a 28-day treatment cycle.

Arm title	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Arm description:

Participants with advanced and/or metastatic platinum-resistant ovarian cancer received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.2 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Arm description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or anaplastic lymphoma kinase (ALK) rearrangements received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 2.2 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg

	1Q3W

Arm description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.8 mg/kg 1Q3W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 1.8 mg/kg was administered intravenously every 3 weeks over a 21-day treatment cycle.

Arm title	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Arm description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Arm type	Experimental
Investigational medicinal product name	Enapotamab vedotin
Investigational medicinal product code	Not applicable
Other name	HuMax®-AXL-ADC
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Enapotamab vedotin 1.0 mg/kg was administered intravenously every week for 3 weeks followed by 1 week without dosing over a 28-day treatment cycle.

Number of subjects in period 1	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W
Started	1	1	3
Completed	0	0	0
Not completed	1	1	3
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	-
Physician decision	-	-	-
Death	-	1	3
Unspecified	-	-	-
Lost to follow-up	-	-	-
Sponsor decision	-	-	-

Number of subjects in period 1	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Started	3	10	11

Completed	0	0	0
Not completed	3	10	11
Adverse event, serious fatal	-	-	2
Consent withdrawn by subject	1	3	1
Physician decision	-	-	-
Death	1	6	8
Unspecified	1	1	-
Lost to follow-up	-	-	-
Sponsor decision	-	-	-

Number of subjects in period 1	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W
Started	3	3	3
Completed	0	0	0
Not completed	3	3	3
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	1	1
Physician decision	-	-	-
Death	1	2	1
Unspecified	-	-	-
Lost to follow-up	-	-	1
Sponsor decision	-	-	-

Number of subjects in period 1	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Started	6	3	22
Completed	0	0	0
Not completed	6	3	22
Adverse event, serious fatal	-	1	2
Consent withdrawn by subject	1	1	12
Physician decision	-	-	-
Death	5	-	6
Unspecified	-	-	-
Lost to follow-up	-	1	1
Sponsor decision	-	-	1

Number of subjects in period 1	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Started	16	25	25
Completed	0	0	0
Not completed	16	25	25

Adverse event, serious fatal	-	4	1
Consent withdrawn by subject	6	6	4
Physician decision	-	-	-
Death	9	13	17
Unspecified	-	-	-
Lost to follow-up	-	-	1
Sponsor decision	1	2	2

Number of subjects in period 1	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Started	44	25	55
Completed	0	0	0
Not completed	44	25	55
Adverse event, serious fatal	4	2	8
Consent withdrawn by subject	5	4	11
Physician decision	1	-	-
Death	26	15	30
Unspecified	1	-	-
Lost to follow-up	1	2	3
Sponsor decision	6	2	3

Number of subjects in period 1	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Started	21	26
Completed	0	0
Not completed	21	26
Adverse event, serious fatal	-	5
Consent withdrawn by subject	4	2
Physician decision	1	1
Death	14	11
Unspecified	-	-
Lost to follow-up	-	-
Sponsor decision	2	7

Baseline characteristics

Reporting groups

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.3 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.5 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.0 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.4 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.8 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.2 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Reporting group description:	
Participants with advanced and/or metastatic NSCLC with classical sensitizing epidermal growth factor receptor (EGFR) mutations and/or EGFR mutations targeted by third-generation tyrosine kinase inhibitors, received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic melanoma with BRAF V600 mutation received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic melanoma with BRAF V600 wild type received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic sarcoma received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Reporting group description:

Participants with advanced and/or metastatic solid tumors (excluding NSCLC, melanoma, sarcoma, and ovarian cancer unless having a known AXL gene amplification) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Reporting group title	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic platinum-resistant ovarian cancer received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or anaplastic lymphoma kinase (ALK) rearrangements received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.8 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Reporting group values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W
Number of subjects	1	1	3
Age categorical			
The data for 'Age categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	0	2
From 65-84 years	0	1	1
85 years and over	0	0	0
Gender categorical			
The data for 'Gender categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
Female	1	1	3
Male	0	0	0

Reporting group values	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Number of subjects	3	10	11
Age categorical			
The data for 'Age categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	9	5
From 65-84 years	1	1	6
85 years and over	0	0	0
Gender categorical			
The data for 'Gender categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
Female	3	7	10
Male	0	3	1

Reporting group values	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W
Number of subjects	3	3	3
Age categorical			
The data for 'Age categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0

Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	1	2
From 65-84 years	1	2	1
85 years and over	0	0	0
Gender categorical			
The data for 'Gender categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
Female	3	2	2
Male	0	1	1

Reporting group values	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Number of subjects	6	3	22
Age categorical			
The data for 'Age categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	3	12
From 65-84 years	2	0	10
85 years and over	0	0	0
Gender categorical			
The data for 'Gender categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
Female	6	3	13
Male	0	0	9

Reporting group values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Number of subjects	16	25	25
Age categorical			
The data for 'Age categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	14	13	15
From 65-84 years	2	12	10
85 years and over	0	0	0
Gender categorical			
The data for 'Gender categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
Female	8	7	14
Male	8	18	11

Reporting group values	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Number of subjects	44	25	55
Age categorical			
The data for 'Age categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	23	16	24
From 65-84 years	21	9	31
85 years and over	0	0	0
Gender categorical			
The data for 'Gender categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
Female	17	25	25
Male	27	0	30

Reporting group values	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Total
Number of subjects	21	26	306
Age categorical			
The data for 'Age categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			

In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	15	17	180
From 65-84 years	6	9	126
85 years and over	0	0	0
Gender categorical			
The data for 'Gender categorical' are reported for participants from the full analysis set, which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).			
Units: Subjects			
Female	11	13	174
Male	10	13	132

End points reporting groups

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.3 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.5 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.0 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.4 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.8 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W
Reporting group description:	
Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.2 mg/kg 3Q4W until the end of treatment.	
Reporting group title	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Reporting group description:	
Participants with advanced and/or metastatic NSCLC with classical sensitizing epidermal growth factor receptor (EGFR) mutations and/or EGFR mutations targeted by third-generation tyrosine kinase inhibitors, received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.	
Reporting group title	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic melanoma with BRAF V600 mutation received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic melanoma with BRAF V600 wild type received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic sarcoma received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Reporting group description:

Participants with advanced and/or metastatic solid tumors (excluding NSCLC, melanoma, sarcoma, and ovarian cancer unless having a known AXL gene amplification) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Reporting group title	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic platinum-resistant ovarian cancer received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or anaplastic lymphoma kinase (ALK) rearrangements received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.8 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Subject analysis set title	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety set was analysed which included all participants who received at least 1 dose of enapotamab vedotin, had at least one valid post-baseline safety assessment, and were classified and were classified according to first dose received.

Subject analysis set title	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety set was analysed which included all participants who received at least 1 dose of enapotamab vedotin, had at least one valid post-baseline safety assessment, and were classified according to first dose received.

Primary: Number of Participants With Dose-limiting Toxicities (DLTs) for Dose-escalation Part

End point title	Number of Participants With Dose-limiting Toxicities (DLTs) for Dose-escalation Part[1][2]

End point description:

The DLTs were defined as Grade (G)4 neutropenia or G4 thrombocytopenia for <=7 days, G3/G4 febrile neutropenia, >=G3 hemorrhage with >=G3 thrombocytopenia, G4 anemia; Stevens Johnson syndrome, toxic epidermal necrolysis, >=G3 cutaneous vasculitis; G3 neuropathy (not improved to G1 within 3 weeks after dose stop), G4 neuropathy; G3 infusion-related reactions (IRR) not resolved to G1/baseline <24 hours; G4 IRR/G4 anaphylaxis events; >= G3 diarrhoea and/or vomiting persisting >48 hours or G3 nausea lasting 7 days (both despite optimal medical management); or any >=G3 related non-hematological AEs, occurred during Cycle 1 and regarded as medically important by Data Monitoring Committee (excluding Grade 3 fatigue or non-hematological laboratory abnormalities). Dose-determining set included participants from Safety set who received at least 1 dose of enapotamab vedotin and either met minimum exposure criterion and completed DLT observation period, or who experienced a DLT during Cycle 1.

End point type	Primary

End point timeframe:

From Day 1 to Day 21 of first cycle for 1Q3W dosing regimen and from Day 1 to Day 28 of first cycle for 3Q4W dosing regimen

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants	0	0	0	0

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	3	3
Units: Participants	1	2	1	0

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	2	

Units: Participants	0	0	2	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs)

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs) and Treatment-emergent Serious Adverse Events (TESAEs)[3][4]

End point description:

An adverse event (AE) is any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. An SAE is defined as an AE that meets one of the following criteria: requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, is a congenital anomaly/birth defect, is medically important, results in death, or is life-threatening. In this trial, a TEAE was defined as an AE occurring or worsening between the first dose of enapotamab vedotin and 30 days after the last dose received. The safety set was analysed which included all participants who received at least 1 dose of enapotamab vedotin, had at least one valid post-baseline safety assessment, and were classified according to first dose received.

End point type	Primary

End point timeframe:

Day 1 through Day 1130 (maximum observed duration)

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants				
Any TEAE	1	1	3	3
Any TESAE	0	0	0	2

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Participants				
Any TEAE	10	11	3	3
Any TESAE	7	6	2	1

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Participants				
Any TEAE	3	6	3	22
Any TESAE	0	2	3	15

End point values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Participants				
Any TEAE	16	25	25	44
Any TESAE	5	16	10	16

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	25	26	56	20
Units: Participants				
Any TEAE	25	26	56	20
Any TESAE	12	14	33	7

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment-emergent Infusion-related AEs and TEAEs Related to Enapotamab Vedotin

End point title	Number of Participants With Treatment-emergent Infusion-related AEs and TEAEs Related to Enapotamab Vedotin[5][6]

End point description:

Number of participants with treatment-emergent infusion-related AEs and TEAEs related to enapotamab vedotin is reported. The safety set was analysed which included all participants who received at least 1 dose of enapotamab vedotin, had at least one valid post-baseline safety assessment, and were classified according to first dose received.

End point type	Primary

End point timeframe:

Day 1 through Day 1130 (maximum observed duration)

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants				
Treatment emergent infusion-related AEs	0	0	0	1
TEAEs related to enapotamab vedotin	1	1	3	3

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Participants				
Treatment emergent infusion-related AEs	0	0	0	0
TEAEs related to enapotamab vedotin	10	10	3	3

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Participants				
Treatment emergent infusion-related AEs	2	1	0	0

TEAEs related to enapotamab vedotin	3	6	3	21

End point values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Participants				
Treatment emergent infusion-related AEs	0	1	2	2
TEAEs related to enapotamab vedotin	15	24	24	38

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	25	26	56	20
Units: Participants				
Treatment emergent infusion-related AEs	0	0	2	1
TEAEs related to enapotamab vedotin	23	20	52	16

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With >= Grade 3 TEAEs as Assessed by National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 4.03

End point title	Number of Participants With >= Grade 3 TEAEs as Assessed by National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 4.03[7][8]

End point description:

Number of participants with TEAEs of >= Grade 3 as assessed by NCI-CTCAE v4.03 is reported. The NCI-CTCAE is a descriptive terminology is used for AE reporting. The NCI-CTCAE v4.03 displays Grades 1 through 5 with unique clinical descriptions of severity for each AE, based on this general guideline: Grade 1 as mild AE, Grade 2 as moderate AE, Grade 3 as severe AE, Grade 4 as life-threatening or disabling AE, and Grade 5 as death. If a participant reported multiple severity grades for an AE, only the maximum grade was used. The safety set was analysed which included all participants who received at least 1 dose of enapotamab vedotin, had at least one valid post-baseline safety assessment, and were classified according to first dose received.

End point type	Primary

End point timeframe:

Day 1 through Day 1130 (maximum observed duration)

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed for this end point.

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

Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants	0	0	0	2

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Participants	7	9	3	1

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Participants	0	3	3	15

End point values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Participants	6	18	16	21

End point values	Expansion Part Cohort 7:	Expansion Part Cohort 8:	Expansion Part Cohort 2:	Expansion Part Cohort 2:

	Enapotamab Vedotin 2.2 mg/kg 1Q3W	Enapotamab Vedotin 1.0 mg/kg 3Q4W	Enapotamab Vedotin 2.2 mg/kg 1Q3W	Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	25	26	56	20
Units: Participants	15	13	40	14

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Grade 3 or 4 Laboratory Results

End point title	Number of Participants With Grade 3 or 4 Laboratory Results[9]

End point description:

Number of participants with laboratory measurements graded as Grade 3 or 4 by NCI-CTCAE v 4.03 is reported. The safety set was analysed which included all participants who received at least 1 dose of enapotamab vedotin, had at least one valid post-baseline safety assessment, and were classified according to first dose received.

End point type	Secondary

End point timeframe:

Day 1 through Day 1130 (maximum observed duration)

Notes:

[9] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants				
Activated partial thromboplastin time	0	0	0	0
Alanine aminotransferase	0	1	0	0
Amylase	0	0	0	0
Aspartate aminotransferase	0	1	0	0
Calcium	0	0	0	0
Gamma-glutamyl transferase	0	1	0	0
Leukocytes	0	0	0	0
Lipase	0	0	0	0
Lymphocytes	1	0	0	0
Magnesium	0	0	0	0
Neutrophils	0	0	0	0
Potassium	0	0	0	0
Prothrombin Intl. Normalized Ratio	0	0	1	0
Sodium	0	0	0	0
Triglycerides	0	0	0	0
Alkaline Phosphatase	0	0	0	0
Hemoglobin	0	0	0	0
Albumin	0	0	0	0

Bilirubin	0	0	0	0
Cholesterol	0	0	0	0

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Participants				
Activated partial thromboplastin time	0	1	1	0
Alanine aminotransferase	0	1	0	0
Amylase	1	0	0	0
Aspartate aminotransferase	0	0	0	0
Calcium	1	0	1	0
Gamma-glutamyl transferase	1	4	1	0
Leukocytes	1	0	0	0
Lipase	1	0	1	0
Lymphocytes	2	2	0	0
Magnesium	1	0	0	0
Neutrophils	4	0	1	0
Potassium	1	1	0	0
Prothrombin Intl. Normalized Ratio	0	1	0	0
Sodium	1	3	1	0
Triglycerides	1	1	0	0
Alkaline Phosphatase	0	0	0	0
Hemoglobin	0	0	0	0
Albumin	0	0	0	0
Bilirubin	0	0	0	0
Cholesterol	0	0	0	0

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Participants				
Activated partial thromboplastin time	0	0	0	0
Alanine aminotransferase	0	0	0	0
Amylase	0	0	0	0
Aspartate aminotransferase	0	0	0	0
Calcium	0	0	1	0
Gamma-glutamyl transferase	1	1	2	5
Leukocytes	0	0	0	0
Lipase	0	0	0	5
Lymphocytes	1	2	0	5

Magnesium	0	0	0	0
Neutrophils	0	0	0	1
Potassium	1	1	0	0
Prothrombin Intl. Normalized Ratio	0	0	0	1
Sodium	0	0	0	1
Triglycerides	0	2	1	0
Alkaline Phosphatase	0	0	1	1
Hemoglobin	0	1	0	1
Albumin	0	0	0	0
Bilirubin	0	0	0	0
Cholesterol	0	0	0	1

End point values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Participants				
Activated partial thromboplastin time	0	0	0	1
Alanine aminotransferase	0	1	1	0
Amylase	0	1	1	1
Aspartate aminotransferase	0	1	0	1
Calcium	0	0	0	1
Gamma-glutamyl transferase	0	3	0	7
Leukocytes	0	2	3	2
Lipase	1	2	1	1
Lymphocytes	0	5	7	9
Magnesium	0	0	0	0
Neutrophils	1	4	7	3
Potassium	0	1	1	1
Prothrombin Intl. Normalized Ratio	0	0	0	1
Sodium	1	1	4	2
Triglycerides	2	2	3	1
Alkaline Phosphatase	0	1	0	1
Hemoglobin	0	1	1	3
Albumin	0	1	1	0
Bilirubin	0	0	0	0
Cholesterol	0	0	0	0

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	25	26	56	20
Units: Participants				

Activated partial thromboplastin time	0	0	2	0
Alanine aminotransferase	0	1	2	0
Amylase	1	1	2	0
Aspartate aminotransferase	1	0	2	0
Calcium	0	1	0	0
Gamma-glutamyl transferase	4	3	8	1
Leukocytes	1	1	2	2
Lipase	3	1	4	3
Lymphocytes	8	4	9	2
Magnesium	1	2	1	0
Neutrophils	5	2	8	2
Potassium	0	1	1	0
Prothrombin Intl. Normalized Ratio	2	1	4	0
Sodium	3	3	7	1
Triglycerides	1	0	1	0
Alkaline Phosphatase	0	1	1	0
Hemoglobin	1	0	2	0
Albumin	0	0	0	0
Bilirubin	1	0	0	0
Cholesterol	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve From Time 0 to Infinity (AUC0-inf) of Conjugated Enapotamab Vedotin for Dose-escalation Part

End point title	Area Under the Plasma Concentration-time Curve From Time 0 to Infinity (AUC0-inf) of Conjugated Enapotamab Vedotin for Dose-escalation Part[10]

End point description:

The AUC0-inf of conjugated enapotamab vedotin for dose-escalation part is reported. The pharmacokinetic (PK) analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, end of infusion (EOI), and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: day*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3)	6.143 (± 99999.0)	13.233 (± 99999.0)	18.353 (± 8.6)	40.921 (± 27.7)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0)	5.780 (± 99999.0)	10.892 (± 99999.0)	18.664 (± 99999.0)	39.589 (± 99999.0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	3	
Units: day*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3)	64.140 (± 13.2)	67.998 (± 32.2)	76.264 (± 31.7)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0)	56.842 (± 23.8)	61.161 (± 10.7)	0 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve From Time 0 to Last Measurable Concentration (AUC0-last) of Conjugated Enapotamab Vedotin for Dose-escalation Part

End point title	Area Under the Plasma Concentration-time Curve From Time 0 to Last Measurable Concentration (AUC0-last) of Conjugated Enapotamab Vedotin for Dose-escalation Part[11]

End point description:

The AUC0-last of conjugated enapotamab vedotin for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3

Notes:

[11] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: day*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3)	5.509 (± 99999.0)	10.369 (± 99999.0)	16.004 (± 18.5)	36.526 (± 29.7)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0)	5.306 (± 99999.0)	9.157 (± 99999.0)	15.047 (± 99999.0)	36.333 (± 99999.0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	3	
Units: day*ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3)	58.410 (± 11.6)	62.563 (± 29.7)	71.196 (± 32.5)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0)	51.541 (± 21.4)	57.759 (± 11.9)	0 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of Conjugated Enapotamab Vedotin for Dose-escalation Part

End point title	Maximum Observed Plasma Concentration (Cmax) of Conjugated Enapotamab Vedotin for Dose-escalation Part[12]

End point description:

The Cmax of conjugated enapotamab vedotin for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here, 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: Predose and EOI on Days 1 and 8 of Cycles 1 and 3; and predose, EOI, and 2 and 5 hours after EOI on Day 15 of Cycles 1 and 3

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n =1, 1, 3, 3, 10, 10, 3, 3, 2, 6, 3)	7.250 (± 99999.0)	12.600 (± 99999.0)	16.615 (± 16.7)	33.005 (± 9.4)
Cycle1 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 3)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 1, 1, 0)	6.870 (± 99999.0)	11.000 (± 99999.0)	16.200 (± 99999.0)	32.400 (± 99999.0)
Cycle3 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n =1, 1, 3, 3, 10, 10, 3, 3, 2, 6, 3)	39.647 (± 11.4)	43.377 (± 25.6)	48.548 (± 33.0)	10.127 (± 40.2)
Cycle1 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 3)	0 (± 0)	0 (± 0)	0 (± 0)	14.201 (± 11.9)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	13.172 (± 8.0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 1, 1, 0)	35.890 (± 17.9)	38.928 (± 9.0)	0 (± 0)	0 (± 0)
Cycle3 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n =1, 1, 3, 3, 10, 10, 3, 3, 2, 6, 3)	14.307 (± 31.6)	18.040 (± 12.0)	17.928 (± 22.0)	
Cycle1 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 3)	16.765 (± 36.3)	18.698 (± 8.1)	18.958 (± 19.5)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	16.166 (± 37.2)	16.991 (± 7.8)	18.500 (± 99999.0)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 1, 1, 0)	22.400 (± 99999.0)	21.800 (± 99999.0)	0 (± 0)	
Cycle3 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 0, 0)	21.200 (± 99999.0)	0 (± 0)	0 (± 0)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	24.100 (± 99999.0)	22.800 (± 99999.0)	0 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Total Clearance (CL) of Conjugated Enapotamab Vedotin in Dose-escalation Part

End point title	Total Clearance (CL) of Conjugated Enapotamab Vedotin in Dose-escalation Part[13]

End point description:

The total CL of conjugated enapotamab vedotin in dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: EOI, and 2 and 5 hours after EOI on Day 15 of Cycles 1 and 3

Notes:

[13] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0	4.053 (± 99999.0)	3.446 (± 99999.0)	3.538 (± 21.8)	2.307 (± 28.3)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	4.360 (± 99999.0)	4.187 (± 99999.0)	3.000 (± 99999.0)	2.160 (± 99999.0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0	2.202 (± 22.2)	2.205 (± 25.4)	1.783 (± 24.3)	0 (± 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	3.679 (± 9.4)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	2.285 (± 27.1)	2.539 (± 14.7)	0 (± 0)	0 (± 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	2.281 (± 99999.0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0	0 (± 0)	0 (± 0)	0 (± 0)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	3.084 (± 93.8)	3.402 (± 31.3)	2.629 (± 99999.0)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	

Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	2.281 (± 99999.0)	3.412 (± 99999.0)	0 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time of Maximum Plasma Concentration (Tmax) of Conjugated Enapotamab Vedotin for Dose-escalation Part

End point title	Time of Maximum Plasma Concentration (Tmax) of Conjugated Enapotamab Vedotin for Dose-escalation Part[14]

End point description:

The Tmax of conjugated enapotamab vedotin for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 15 of Cycles 1 and 3

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	0.06 (0.06 to 0.06)	0.03 (0.03 to 0.03)	0.036 (0.03 to 0.04)	0.033 (0.03 to 0.04)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	0.04 (0.04 to 0.04)	0.03 (0.03 to 0.03)	0.04 (0.04 to 0.04)	0.030 (0.03 to 0.03)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3

Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	0.032 (0.02 to 0.09)	0.032 (0.02 to 0.04)	0.03 (0.02 to 0.03)	0 (0 to 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	14.010 (13.96 to 14.88)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	0.036 (0.02 to 0.05)	0.042 (0.03 to 0.11)	0 (0 to 0)	0 (0 to 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	14.058 (13.98 to 14.08)	14.083 (14.00 to 14.19)	13.98 (13.98 to 13.98)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	14.02 (14.02 to 14.02)	13.98 (13.98 to 13.98)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Half-life Lambda-z (t1/2) of Conjugated Enapotamab Vedotin for Dose-escalation Part

End point title	Half-life Lambda-z (t1/2) of Conjugated Enapotamab Vedotin for Dose-escalation Part[15]

End point description:

The t1/2 of conjugated enapotamab vedotin for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 15 of Cycles 1 and 3

Notes:

[15] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	0.87 (0.87 to 0.87)	1.49 (1.49 to 1.49)	1.362 (1.02 to 1.39)	1.384 (1.19 to 1.65)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	0.78 (0.78 to 0.78)	1.07 (1.07 to 1.07)	1.130 (1.13 to 1.13)	1.68 (1.68 to 1.68)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	2.004 (1.67 to 2.53)	1.810 (1.53 to 2.74)	2.153 (1.99 to 2.60)	0 (0 to 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	1.097 (0.66 to 1.56)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	2.117 (1.55 to 2.90)	2.035 (1.38 to 2.74)	0 (0 to 0)	0 (0 to 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	1.398 (0.91 to 1.81)	1.423 (0.77 to 1.96)	2.05 (2.05 to 2.05)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	1.51 (1.51 to 1.51)	1.44 (1.44 to 1.44)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution at Steady State (Vss) of Conjugated Enapotamab Vedotin for Dose-escalation Part

End point title	Volume of Distribution at Steady State (Vss) of Conjugated Enapotamab Vedotin for Dose-escalation Part[16]

End point description:

The Vss of conjugated enapotamab vedotin for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 15 of Cycles 1 and 3

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	4.909 (± 99999.0)	6.544 (± 99999.0)	5.873 (± 9.8)	4.208 (± 12.5)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	4.755 (± 99999.0)	6.288 (± 99999.0)	4.870 (± 99999.0)	4.534 (± 99999.0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	6.028 (± 18.4)	5.489 (± 24.2)	5.038 (± 27.3)	0 (± 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	57.736 (± 10.0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	6.072 (± 24.2)	6.656 (± 22.0)	0 (± 0)	0 (± 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	48.001 (± 91.1)	53.436 (± 28.0)	42.708 (± 99999.0)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 0, 0, 0, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	36.476 (± 99999.0)	53.085 (± 99999.0)	0 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: AUC0-inf of Free Toxin Monomethyl Auristatin E (MMAE) for Dose-escalation Part

End point title	AUC0-inf of Free Toxin Monomethyl Auristatin E (MMAE) for Dose-escalation Part[17]

End point description:

The AUC0-inf of MMAE for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3

Notes:

[17] - 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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Day*pg/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 2)	3832.48 (± 99999)	6144.11 (± 99999)	13673.7 (± 110.4)	26549.1 (± 82.9)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1)	3248.46 (± 99999)	7452.05 (± 99999)	4338.20 (± 99999)	47093.9 (± 99999)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	3	
Units: Day*pg/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 2)	33494.5 (± 47.1)	50459.6 (± 117.0)	48626.4 (± 95.5)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1)	30512.0 (± 47.8)	34188.6 (± 46.6)	16754.5 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: AUC0-last of MMAE for Dose-escalation Part

End point title	AUC0-last of MMAE for Dose-escalation Part[18]

End point description:

The AUC0-last of MMAE for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: day*pg/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3)	3364.64 (± 99999.0)	5980.86 (± 99999.0)	13194.4 (± 110.4)	25549.3 (± 80.8)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1)	2642.23 (± 99999.0)	7263.16 (± 99999.0)	4156.66 (± 99999.0)	44553.3 (± 99999.0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	11	3	
Units: day*pg/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n = 1, 1, 3, 3, 10, 10, 3)	31854.7 (± 46.4)	34659.4 (± 81.2)	38963.5 (± 65.4)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1)	28890.0 (± 47.4)	31429.9 (± 43.2)	16354.3 (± 99999.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of MMAE for Dose-escalation Part

End point title	Cmax of MMAE for Dose-escalation Part[19]

End point description:

The Cmax of MMAE for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: Predose and EOI on Days 1 and 8 of Cycles 1 and 3; and predose, EOI, and 2

and 5 hours after EOI on Day 15 of Cycles 1 and 3

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: pg/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 3, 3, 6, 3)	700.000 (± 99999.0)	947.000 (± 99999.0)	1847.13 (± 149.5)	4036.47 (± 81.8)
Cycle1 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 3)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 1, 1, 0)	631.000 (± 99999.0)	1200.00 (± 99999.0)	628.000 (± 99999.0)	6500.00 (± 99999.0)
Cycle3 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: pg/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 3, 3, 6, 3)	4265.60 (± 46.1)	5154.48 (± 61.9)	5617.89 (± 34.7)	161.140 (± 75.0)
Cycle1 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 3)	0 (± 0)	0 (± 0)	0 (± 0)	738.227 (± 28.2)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (± 0)	0 (± 0)	0 (± 0)	1715.54 (± 42.8)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 1, 1, 0)	3964.40 (± 49.4)	4127.31 (± 39.3)	2180.00 (± 99999.0)	0 (± 0)
Cycle3 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: pg/mL				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 3, 3, 6, 3)	175.315 (± 159.4)	303.977 (± 45.3)	244.623 (± 48.9)	
Cycle1 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 3)	766.467 (± 91.4)	1982.67 (± 58.1)	1553.93 (± 86.2)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	2525.75 (± 54.7)	4379.50 (± 58.2)	3720.00 (± 99999.0)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 1, 1, 0)	442.000 (± 99999.0)	558.000 (± 99999.0)	0 (± 0)	
Cycle3 Day8 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 0, 0)	1060.00 (± 99999.0)	0 (± 0)	0 (± 0)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	2960.00 (± 99999.0)	5190.00 (± 99999.0)	0 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Total CL of MMAE in Dose-escalation Part

End point title	Total CL of MMAE in Dose-escalation Part[20]

End point description:

The total CL of MMAE in dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point. The arbitrary number '99999.0' denotes the data for geometric coefficient of variation, which was not determined because an insufficient number of participants was evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: EOI, and 2 and 5 hours after EOI on Day 15 of Cycles 1 and 3

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: L/day				
geometric mean (geometric coefficient of variation)				

Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 2, 0, 0, 0, 0)	6497.09 (± 99999.0)	7421.74 (± 99999.0)	4748.64 (± 87.2)	3555.78 (± 90.6)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	7757.51 (± 99999.0)	6119.12 (± 99999.0)	12908.6 (± 99999.0)	1815.52 (± 99999.0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 2, 0, 0, 0, 0)	4216.71 (± 42.0)	2971.09 (± 107.2)	2813.05 (± 35.9)	0 (± 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 0)	0 (± 0)	0 (± 0)	0 (± 0)	4819.44 (± 25.8)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	4256.44 (± 50.1)	4542.22 (± 42.8)	5849.18 (± 99999.0)	0 (± 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: L/day				
geometric mean (geometric coefficient of variation)				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 2, 0, 0, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 0)	4666.23 (± 35.5)	2847.55 (± 46.7)	0 (± 0)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	0 (± 0)	0 (± 0)	0 (± 0)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	3899.39 (± 99999.0)	2507.90 (± 99999.0)	0 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax of MMAE for Dose-escalation Part

End point title	Tmax of MMAE for Dose-escalation Part[21]

End point description:

The Tmax of MMAE for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	2.95 (2.95 to 2.95)	3.00 (3.00 to 3.00)	2.938 (2.89 to 2.94)	2.764 (2.72 to 2.83)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	2.83 (2.83 to 2.83)	2.87 (2.87 to 2.87)	0.94 (0.94 to 0.94)	2.83 (2.83 to 2.83)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	2.852 (0.97 to 3.03)	2.866 (1.00 to 6.85)	2.942 (2.82 to 7.00)	0 (0 to 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	15.950 (15.93 to 17.73)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	2.830 (0.94 to 3.96)	2.727 (0.94 to 2.94)	3.02 (3.02 to 3.02)	0 (0 to 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 3, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 1)	15.982 (15.97 to 15.99)	15.911 (14.51 to 15.95)	20.820 (20.82 to 20.82)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	14.93 (14.93 to 14.93)	15.890 (15.89 to 15.89)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of MMAE for Dose-escalation Part

End point title	t1/2 of MMAE for Dose-escalation Part[22]

End point description:

The t1/2 of MMAE for dose-escalation part is reported. The PK analysis set was analysed which included all participants who were exposed to at least 1 dose of enapotamab vedotin and who had at least 1 postdose PK measurement. Here 'n' denotes the number of participants evaluated for the specified time point.

End point type	Secondary

End point timeframe:

For 1Q3W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 1 of Cycles 1 and 3; For 3Q4W dosing regimen: Predose, EOI, and 2 and 5 hours after EOI on Day 15 of Cycles 1 and 3

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 2, 0, 0, 0, 0)	2.19 (2.19 to 2.19)	2.35 (2.35 to 2.35)	2.470 (2.10 to 2.70)	2.620 (1.85 to 2.98)

Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	1.94 (1.94 to 1.94)	2.32 (2.32 to 2.32)	2.71 (2.71 to 2.71)	2.52 (2.52 to 2.52)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 2, 0, 0, 0, 0)	2.420 (2.02 to 3.75)	3.128 (1.55 to 42.73)	2.835 (2.45 to 3.22)	0 (0 to 0)
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	3.976 (2.78 to 6.06)
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	2.746 (2.18 to 3.12)	3.364 (2.85 to 4.99)	1.98 (1.98 to 1.98)	0 (0 to 0)
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	6	3	
Units: Day				
median (full range (min-max))				
Cycle1 Day1 (n= 1, 1, 3, 3, 10, 10, 2, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
Cycle1 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 3, 3, 6, 0)	3.115 (2.49 to 5.04)	4.739 (2.85 to 8.70)	0 (0 to 0)	
Cycle3 Day1 (n = 1, 1, 1, 1, 8, 4, 1, 0, 0, 0, 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 00)	
Cycle3 Day15 (n = 0, 0, 0, 0, 0, 0, 0, 0, 1, 1, 0)	2.330 (2.33 to 2.33)	3.37 (3.37 to 3.37)	0 (0 to 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Antidrug Antibodies (ADAs) Confirmed Positive to Enapotamab Vedotin

End point title	Number of Participants With Antidrug Antibodies (ADAs)

	Confirmed Positive to Enapotamab Vedotin[23]

End point description:

The ADA assessment was performed according to a tiered approach. First samples were screened for an ADA response; positively screened samples were analysed in a confirmation method. Subsequently confirmed positive samples were analysed for titre and the presence of neutralizing antibodies. The number of participants with ADA confirmed positive to enapotamab vedotin is reported. The safety set was analysed which included all participants who received at least 1 dose of enapotamab vedotin, had at least one valid post-baseline safety assessment, and were classified according to first dose received.

End point type	Secondary

End point timeframe:

Day 1 through Day 1130 (Dose-escalation part: Predose of Day 1 of Cycles 1 to 12, end of treatment [EOT], and 30 days after last study drug; Expansion part: Predose on Day 1 of Cycles 1 to 5, then every fourth cycle until PD)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants	0	0	1	1

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Participants	5	1	1	0

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Participants	0	2	0	0

End point values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2	Expansion Part Cohort 4: Enapotamab Vedotin 2.2	Expansion Part Cohort 5: Enapotamab Vedotin 2.2	Expansion Part Cohort 6: Enapotamab Vedotin 1.0

	mg/kg 1Q3W	mg/kg 1Q3W	mg/kg 1Q3W	mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Participants	4	1	3	0

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	25	26	56	20
Units: Participants	7	0	5	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Objective Response (OR) Based on Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) As Assessed by Investigator

End point title	Number of Participants With Objective Response (OR) Based on Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) As Assessed by Investigator

End point description:

Radiological evaluation based on RECIST v1.1 was performed by the investigator using computed tomography (CT) scans/ magnetic resonance imaging (MRI) scans/ positron emission tomography (PET) scans. The OR was defined as confirmed CR or confirmed PR per RECIST v1.1. The changes in tumor measurements that were confirmed by repeat assessments performed no less than 4 weeks after initial response are called confirmed responses. The CR was defined as disappearance of all target and non-target lesions and all pathological lymph nodes must have decreased to < 10 mm in short axis. The PR was defined as at least a 30% decrease in the sum of the longest diameters (LD) of target lesions taking as reference the baseline sum of LD. The full analysis set was analysed which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule).

End point type	Secondary

End point timeframe:

Day 1 through 44.5 months (maximum observed duration)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants	0	0	0	1

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Participants	0	1	1	0

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Participants	0	0	0	1

End point values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Participants	2	3	0	4

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	55	21	26
Units: Participants	2	5	1	3

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Best Cancer Antigen 125 (CA-125) Response

End point title	Number of Participants With Best Cancer Antigen 125 (CA-125) Response[24]

End point description:

The best CA-125 response was evaluated in participants with ovarian cancer. A CA-125 partial response was defined as at least a 50% reduction in CA-125 levels in blood from a pretreatment sample. Participants who had a CA-125 partial response and had CA-125 level falls to within the reference range (0-35 units/mL) were classified as CA-125 complete responders. The response was confirmed and maintained for at least 28 days. The best overall response (CA-125 partial response and CA-125 complete response) is reported. Participants from the full analysis set with ovarian cancer who had an initial CA-125 level of at least twice the upper limit of the reference range within 2 weeks before starting the study treatment were evaluated for this end point.

End point type	Secondary

End point timeframe:

From Screening (within 2 weeks before starting of the study treatment) through Day 1130 (maximum observed duration)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Participants				
CA-125 partial response	0	0	0	0
CA-125 complete response	0	0	0	0

End point values	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	2
Units: Participants				
CA-125 partial response	1	0	0	0
CA-125 complete response	0	0	0	0

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Participants				
CA-125 partial response	2			

CA-125 complete response	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR) Based on RECIST v1.1 as Assessed by Investigator for Expansion Part

End point title	Duration of Response (DoR) Based on RECIST v1.1 as Assessed by Investigator for Expansion Part[25]

End point description:

The DoR was defined as number of months from first documentation of OR (confirmed CR or confirmed PR) to the date of first progressive disease (PD) or death. The OR was defined in the earlier end point. The PD was defined as at least 20% increase in the sum of LD of target lesions taking as reference the smallest sum of the LD recorded since the treatment started or the appearance of one or more new target and non-target lesions and/or unequivocal progression of existing non-target lesions. Participants from the full analysis set who achieved confirmed OR by the investigator assessment were evaluated for this end point. Here, the arbitrary number '999.0' denotes the data for median and '0.9999' and '9999.9' denote the lower and upper limits of confidence interval, respectively, which were not determined because an insufficient number of participants was evaluated.

End point type	Secondary

End point timeframe:

Day 1 through 44.5 months (maximum observed duration)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[26]	1	2	0[27]
Units: Months				
median (confidence interval 95%)	(to)	4.2 (0.9999 to 9999.9)	4.1 (2.4 to 9999.9)	(to)

Notes:

[26] - No participants with confirmed OR by the investigator assessment.

[27] - No participants with confirmed OR by the investigator assessment.

End point values	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	1
Units: Months				
median (confidence interval 95%)	4.9 (2.6 to	3.0 (0.9999 to	999.0 (3.0 to	3.0 (0.9999 to

	9999.9)	9999.9)	9999.9)	9999.9)

End point values	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Months				
median (confidence interval 95%)	4.9 (0.9999 to 9999.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS) as Assessed by Investigator

End point title	Progression Free Survival (PFS) as Assessed by Investigator

End point description:

The PFS was defined as the number of months from the date of first study drug administration to first PD or death. The PD was defined as at least 20% increase in the sum of longest diameters of target lesions taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions. The PFS was estimated using Kaplan-Meier method. The full analysis set was analysed which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule). Here, the arbitrary numbers '0.9999' and '9999.9' denote the lower and upper limits of confidence interval, respectively and '999.0' denotes the data for median, which were not determined because an insufficient number of participants was evaluated.

End point type	Secondary

End point timeframe:

Day 1 through 44.5 months (maximum observed duration)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Months				
median (confidence interval 95%)	6.7 (0.9999 to 9999.9)	3.5 (0.9999 to 9999.9)	1.3 (1.2 to 9999.9)	5.3 (1.1 to 9999.9)

End point values	Dose-escalation Part: Enapotamab	Dose-escalation Part: Enapotamab	Dose-escalation Part: Enapotamab	Dose-escalation Part: Enapotamab

	Vedotin 2.0 mg/kg 1Q3W	Vedotin 2.2 mg/kg 1Q3W	Vedotin 2.4 mg/kg 1Q3W	Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Months				
median (confidence interval 95%)	2.8 (1.4 to 9999.9)	2.6 (0.7 to 9999.9)	999.0 (0.9999 to 9999.9)	1.6 (0.9999 to 9999.9)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Months				
median (confidence interval 95%)	1.6 (1.3 to 9999.9)	4.3 (1.0 to 9999.9)	0.8 (0.4 to 9999.9)	2.6 (1.2 to 2.8)

End point values	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Months				
median (confidence interval 95%)	2.6 (1.2 to 3.9)	2.8 (1.3 to 5.0)	2.6 (1.4 to 4.1)	1.9 (1.6 to 2.1)

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	55	21	26
Units: Months				
median (confidence interval 95%)	1.6 (1.3 to 3.0)	2.2 (1.4 to 3.9)	2.6 (1.1 to 4.0)	2.0 (1.4 to 4.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

Overall survival was defined as the number of months from date of first study drug administration to death. The OS was estimated using Kaplan-Meier method. The full analysis set was analysed which included all participants who received at least 1 dose of enapotamab vedotin and were analysed according to the assigned treatment/dose (planned dose level and schedule). Here, the arbitrary numbers '0.9999' and '9999.9' denote the lower and upper limits of confidence interval, respectively and '999.0' denotes the data for median, which were not determined because an insufficient number of participants was evaluated.

End point type	Secondary

End point timeframe:

Day 1 through 44.5 months (maximum observed duration)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	3
Units: Months				
median (confidence interval 95%)	999.0 (0.9999 to 9999.9)	4.3 (0.9999 to 9999.9)	6.4 (6.3 to 9999.9)	999.0 (6.7 to 9999.9)

End point values	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	3	3
Units: Months				
median (confidence interval 95%)	14.5 (3.1 to 9999.9)	7.6 (2.2 to 12.1)	44.5 (0.9999 to 9999.9)	6.7 (6.7 to 9999.9)

End point values	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	3	22
Units: Months				
median (confidence interval 95%)	14.3 (0.9999 to 9999.9)	7.7 (4.3 to 9999.9)	21.7 (0.4 to 9999.9)	16.5 (4.1 to 25.9)

End point values	Expansion Part Cohort 3: Enapotamab	Expansion Part Cohort 4: Enapotamab	Expansion Part Cohort 5: Enapotamab	Expansion Part Cohort 6: Enapotamab

	Vedotin 2.2 mg/kg 1Q3W	Vedotin 2.2 mg/kg 1Q3W	Vedotin 2.2 mg/kg 1Q3W	Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	25	25	44
Units: Months				
median (confidence interval 95%)	8.6 (3.6 to 19.1)	9.2 (4.0 to 14.9)	17.1 (5.7 to 24.3)	7.0 (5.2 to 11.6)

End point values	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	55	21	26
Units: Months				
median (confidence interval 95%)	8.4 (6.5 to 12.4)	11.3 (8.0 to 15.5)	8.7 (5.8 to 14.1)	8.0 (4.1 to 12.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Change in AXL Expression (Total Tumor H-score) From Baseline to EOT Visit for Expansion Part

End point title	Change in AXL Expression (Total Tumor H-score) From Baseline to EOT Visit for Expansion Part[28]

End point description:

Change in AXL expression (total humor H-score in membrane or cytoplasm) from baseline to EOT visit for the expansion part is reported. The H-score captures both the intensity and proportion of AXL positive tumor cells and was defined by the formula: H-score = (1 × % 1+ tumor cells) + (2 × % 2+ tumor cells) + (3 × % 3+ tumor cells); where '1+' indicates weak staining intensity, '2+' indicates medium staining intensity, and '3+' indicates strong staining intensity. The H-score values ranges from 0 to 300. Lower H-scores represent lower AXL expression in the tumor sample, while higher scores represent stronger AXL expression in the tumor samples. Participants from the full analysis set who had tumor H-scores in membrane/cytoplasm assessed at Baseline and at the EOT visit were evaluated. The arbitrary number '99999.9' denotes data for standard deviation, which was not determined because an insufficient participants was evaluated.

End point type	Secondary

End point timeframe:

Baseline (Study Days -21 to 1) and EOT visit (Day 1100)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	0[29]	1
Units: Scores on a scale				
arithmetic mean (standard error)	-8.0 (± 99999.9)	-1.0 (± 99999.9)	()	-30.0 (± 99999.9)

Notes:

[29] - No participant had tumor H-score in membrane/cytoplasm at Baseline and EOT visit.

End point values	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[30]	1	1	0[31]
Units: Scores on a scale				
arithmetic mean (standard error)	()	35.0 (± 99999.9)	-14.0 (± 99999.9)	()

Notes:

[30] - No participant had tumor H-score in membrane/cytoplasm at Baseline and EOT visit.

[31] - No participant had tumor H-score in membrane/cytoplasm at Baseline and EOT visit.

End point values	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W			
Subject group type	Reporting group			
Number of subjects analysed	0[32]			
Units: Scores on a scale				
arithmetic mean (standard error)	()			

Notes:

[32] - No participant had tumor H-score in membrane/cytoplasm at Baseline and EOT visit.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

For TEAEs: Day 1 through Day 1130 and for all-cause mortality: From date of inform consent form until death (up to 44.5 months) (maximum observed duration)

Adverse event reporting additional description:

The TEAEs were evaluated per the safety set and all-cause mortality was evaluated per the full analysis set.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v24.0

Reporting groups

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.3 mg/kg 1Q3W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 1Q3W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 1Q3W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.5 mg/kg 1Q3W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.0 mg/kg 1Q3W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 2.4 mg/kg 1Q3W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.6 mg/kg 3Q4W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 0.8 mg/kg 3Q4W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or

melanoma) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Reporting group title	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W

Reporting group description:

Participants with relapsed/refractory cancer (ovarian, cervical, endometrial, thyroid, NSCLC, or melanoma) received IV infusion of enapotamab vedotin 1.2 mg/kg 3Q4W until the end of treatment.

Reporting group title	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic NSCLC with classical sensitizing EGFR mutations and/or EGFR mutations targeted by third-generation tyrosine kinase inhibitors) received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic melanoma with BRAF V600 mutation received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic melanoma with BRAF V600 wild type received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic sarcoma received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Reporting group description:

Participants with advanced and/or metastatic solid tumors (excluding NSCLC, melanoma, sarcoma, and ovarian cancer unless having a known AXL gene amplification) received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Reporting group title	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic platinum-resistant ovarian cancer received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.0 mg/kg 3Q4W until the end of treatment.

Reporting group title	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 2.2 mg/kg 1Q3W until the end of treatment.

Reporting group title	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W

Reporting group description:

Participants with advanced and/or metastatic NSCLC without activating EGFR mutations or ALK rearrangements received IV infusion of enapotamab vedotin 1.8 mg/kg 1Q3W until the end of treatment.

Serious adverse events	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	1	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis Carcinomatosa			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Neoplasm Progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases To Central Nervous System			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Peritoneum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion Malignant			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Deep Vein Thrombosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Chest Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Physical Health Deterioration			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Like Illness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Acute Respiratory Failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal Obstruction Extrinsic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Confusional State			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Occlusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Creatinine Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lymphocyte Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Tamponade			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Partial Seizures			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Abdominal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Biliary Obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal Vein Thrombosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Bacteraemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis Infective			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
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	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	7 / 10 (70.00%)	6 / 11 (54.55%)
number of deaths (all causes)	1	6	10
number of deaths resulting from adverse events	0	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis Carcinomatosa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Neoplasm Progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Metastases To Central Nervous System			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Peritoneum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Progression			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion Malignant			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Physical Health Deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Like Illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (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			

Acute Respiratory Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Embolism			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal Obstruction Extrinsic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Confusional State			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Creatinine Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Monoplegia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial Seizures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (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
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	4 / 10 (40.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	4 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (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
Intestinal Obstruction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis Infective			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 Infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (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
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
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	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 3 (0.00%)
number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis Carcinomatosa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Neoplasm Progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases To Central Nervous System			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Peritoneum			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion Malignant			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			

Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Physical Health Deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Like Illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Acute Respiratory Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal Obstruction Extrinsic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Confusional State			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			

Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Creatinine Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hip Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Loss of Consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial Seizures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Biliary Obstruction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis Infective			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	3 / 3 (100.00%)	15 / 22 (68.18%)
number of deaths (all causes)	5	1	8
number of deaths resulting from adverse events	0	1	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis Carcinomatosa			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 Neoplasm Progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases To Central Nervous System			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Peritoneum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion Malignant			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
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			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Chest Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General Physical Health Deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 Like Illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Acute Respiratory Failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 Aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 Embolism			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	3 / 22 (13.64%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tracheal Obstruction Extrinsic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Confusional State			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device Occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 Creatinine Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Fall			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 Tamponade			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial Seizures			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (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
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Abdominal Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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	1 / 6 (16.67%)	0 / 3 (0.00%)	7 / 22 (31.82%)
occurrences causally related to treatment / all	1 / 1	0 / 0	7 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary Obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (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
Portal Vein Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (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
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis Infective			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (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
Septic Shock			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (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
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (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	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 16 (31.25%)	16 / 25 (64.00%)	10 / 25 (40.00%)
number of deaths (all causes)	9	17	18
number of deaths resulting from adverse events	0	4	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis Carcinomatosa			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 Neoplasm Progression			
subjects affected / exposed	0 / 16 (0.00%)	4 / 25 (16.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Metastases To Central Nervous System			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Metastases to Peritoneum			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Progression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion Malignant			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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			
Chest Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
General Physical Health Deterioration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 Like Illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 Aspiration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal Obstruction Extrinsic			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Occlusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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			
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Blood Creatinine Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

White Blood Cell Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	0 / 25 (0.00%)
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 Tamponade			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	0 / 25 (0.00%)
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			
Acute Motor-Sensory Axonal Neuropathy			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial Seizures			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Motor Neuropathy			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (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
Seizure			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (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
Gastrointestinal disorders			

Abdominal Pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Abdominal Pain Upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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	4 / 16 (25.00%)	4 / 25 (16.00%)	3 / 25 (12.00%)
occurrences causally related to treatment / all	4 / 4	4 / 4	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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			
Biliary Obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal Vein Thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Adrenal Insufficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (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
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 25 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Cholangitis Infective			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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%)	1 / 25 (4.00%)	0 / 25 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
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	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 44 (36.36%)	12 / 25 (48.00%)	14 / 26 (53.85%)
number of deaths (all causes)	30	17	16
number of deaths resulting from adverse events	4	2	5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis Carcinomatosa			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 Neoplasm Progression			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Metastases To Central Nervous System			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Peritoneum			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Progression			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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
Pericardial Effusion Malignant			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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
Hypertension			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
Chest Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Fatigue			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General Physical Health Deterioration			
subjects affected / exposed	0 / 44 (0.00%)	3 / 25 (12.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Influenza Like Illness			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Respiratory Failure			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dysphonia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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	1 / 44 (2.27%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypoxia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia Aspiration			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal Obstruction Extrinsic			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
Confusional State			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Occlusion			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (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
Investigations			
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 Creatinine Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lipase Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (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
Femoral Neck Fracture			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 Tamponade			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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
Nervous system disorders			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (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
Cerebrovascular Accident			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (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
Monoplegia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (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

Neuralgia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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
Partial Seizures			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
Abdominal Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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	2 / 44 (4.55%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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
Ileus			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	1 / 44 (2.27%)	2 / 25 (8.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (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
Hepatobiliary disorders			
Biliary Obstruction			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (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
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal Vein Thrombosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis Infective			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic Sepsis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 Infection			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (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	2 / 44 (4.55%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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 / 44 (0.00%)	2 / 25 (8.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 1
Staphylococcal Bacteraemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
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	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W	
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 56 (58.93%)	7 / 20 (35.00%)	
number of deaths (all causes)	38	14	
number of deaths resulting from adverse events	8	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis Carcinomatosa			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Neoplasm Progression			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Metastases To Central Nervous System			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to Peritoneum			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm Progression			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial Effusion Malignant			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Embolism			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Death			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General Physical Health Deterioration			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza Like Illness			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Acute Respiratory Failure			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dysphonia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Aspiration			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary Embolism			

subjects affected / exposed	4 / 56 (7.14%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tracheal Obstruction Extrinsic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental Status Changes			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic Disorder			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device Occlusion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood Creatinine Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipase Increased			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil Count Decreased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral Neck Fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Tamponade			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular Tachycardia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Acute Motor-Sensory Axonal Neuropathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular Accident			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of Consciousness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Monoplegia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial Seizures			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient Ischaemic Attack			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile Neutropenia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain Upper			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal Obstruction			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	4 / 56 (7.14%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	1 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Intestinal Obstruction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary Obstruction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-Induced Liver Injury			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal Vein Thrombosis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Myalgia			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis Infective			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower Respiratory Tract Infection			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic Sepsis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis Jirovecii Infection			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sepsis			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 1	
Septic Shock			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Staphylococcal Bacteraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			

subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Dose-escalation Part: Enapotamab Vedotin 0.3 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 1Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jugular Vein Thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular Compression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application Site Reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Axillary Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Condition Aggravated			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Face Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	2 / 3 (66.67%)
occurrences (all)	1	1	3
Feeling Abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait Disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hernia Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised Oedema			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical Device Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac Chest Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Physical Deconditioning			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Soft Tissue Inflammation			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temperature Intolerance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaccination Site Reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Perineal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal Discharge			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vulvovaginal Dryness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adductor Vocal Cord Weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Dysaesthesia Pharynx			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea Exertional			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paranasal Sinus Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleuritic Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia Aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary Haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vasomotor Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional State			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Delirium			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed Mood			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, Olfactory			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mental Status Changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Amylase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood Albumin Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood Bilirubin Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood Iron Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Magnesium Decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Phosphorus Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Urea Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breath Sounds Abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive Protein Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase Increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glomerular Filtration Rate Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase Increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 Test Positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcus Test Positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin T Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Weight Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Compression Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip Injury			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post Procedural Swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Radiation Necrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tendon Rupture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial Effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular Extrasystoles			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amputation Stump Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Autonomic Nervous System Imbalance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Autonomic Neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed Level of Consciousness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic Encephalopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mononeuropathy			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Monoplegia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Neuropathy Peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paresis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal Cord Compression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Anaemia Macrocytic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia of Chronic Disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Coagulopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Febrile Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Normocytic Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Borderline Glaucoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eye Irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Photopsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trichomegaly			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous Floaters			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cheilitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Duodenogastric Reflux			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epigastric Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gastritis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiatus Hernia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia Teeth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Impaired Gastric Emptying			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intestinal Obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Neutropenic Colitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary Duct Inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic Failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic Steatosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Hepatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Bullous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema Multiforme			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lichenoid Keratosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail Discolouration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail Dystrophy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Rash Erythematous			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Macular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bladder Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Calculus Bladder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urge Incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Bone Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mobility Decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Muscle Tightness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Neck Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pain in Extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Citrobacter Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Cystitis Escherichia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Epididymitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal Oesophagitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes Simplex			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung Abscess			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Pustular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Urinary Tract Candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fluid Overload			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hypophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose-escalation Part: Enapotamab Vedotin 1.5 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.0 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	10 / 10 (100.00%)	11 / 11 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	1	1	1

Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Jugular Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Orthostatic Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Vascular Compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application Site Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Axillary Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Chest Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Chest Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Condition Aggravated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Face Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	5 / 10 (50.00%)	8 / 11 (72.73%)
occurrences (all)	3	5	10
Feeling Abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gait Disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hernia Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Localised Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Medical Device Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Non-cardiac Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Physical Deconditioning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	0 / 11 (0.00%)
occurrences (all)	3	2	0
Soft Tissue Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Temperature Intolerance			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vaccination Site Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Breast Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Perineal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vaginal Discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal Dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adductor Vocal Cord Weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Dysaesthesia Pharynx			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	3 / 11 (27.27%)
occurrences (all)	1	0	3
Dyspnoea Exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypoventilation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Paranasal Sinus Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleuritic Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumonia Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pulmonary Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pulmonary Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus Disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Sinus Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vasomotor Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Confusional State			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Depressed Mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hallucination, Olfactory			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	1	1	2
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mental Status Changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	4 / 11 (36.36%)
occurrences (all)	0	1	5
Amylase Increased			

subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	0 / 11 (0.00%)
occurrences (all)	0	3	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	3 / 11 (27.27%)
occurrences (all)	0	9	4
Blood Albumin Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	2 / 11 (18.18%)
occurrences (all)	0	1	2
Blood Bilirubin Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Blood Creatinine Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Blood Iron Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Magnesium Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Phosphorus Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood Urea Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Breath Sounds Abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
C-reactive Protein Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	3 / 11 (27.27%)
occurrences (all)	0	2	4
Glomerular Filtration Rate Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lipase Increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 Test Positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Staphylococcus Test Positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Troponin T Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Troponin Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Vitamin B12 Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	4 / 11 (36.36%)
occurrences (all)	0	2	4

Weight Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Compression Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Lip Injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Lumbar Vertebral Fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Post Procedural Swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Radiation Necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tendon Rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Pericardial Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ventricular Extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nervous system disorders			
Amputation Stump Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Autonomic Nervous System Imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Autonomic Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Balance Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Depressed Level of Consciousness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	3
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	3 / 11 (27.27%)
occurrences (all)	0	1	4
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolic Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mononeuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Monoplegia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neuropathy Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paresis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	5 / 10 (50.00%)	2 / 11 (18.18%)
occurrences (all)	0	6	4
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Spinal Cord Compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Taste Disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	4 / 10 (40.00%)	1 / 11 (9.09%)
occurrences (all)	2	8	1
Anaemia Macrocytic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anaemia of Chronic Disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Febrile Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	0 / 11 (0.00%)
occurrences (all)	0	4	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	4 / 10 (40.00%)	2 / 11 (18.18%)
occurrences (all)	4	29	3
Normocytic Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Borderline Glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Eye Irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Trichomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Visual Impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vitreous Floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	6 / 10 (60.00%)	4 / 11 (36.36%)
occurrences (all)	0	8	7
Abdominal Pain Lower			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain Upper			
subjects affected / exposed	1 / 3 (33.33%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Colitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	8 / 10 (80.00%)	7 / 11 (63.64%)
occurrences (all)	1	14	10
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	5 / 10 (50.00%)	7 / 11 (63.64%)
occurrences (all)	1	11	13
Dry Mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Duodenogastric Reflux			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	2 / 11 (18.18%)
occurrences (all)	2	2	2
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Epigastric Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastric Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Gingival Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gingival Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hiatus Hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hyperaesthesia Teeth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Impaired Gastric Emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Intestinal Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	6 / 10 (60.00%)	7 / 11 (63.64%)
occurrences (all)	4	9	17
Neutropenic Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Salivary Duct Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	2 / 3 (66.67%)	6 / 10 (60.00%)	7 / 11 (63.64%)
occurrences (all)	4	13	11
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatic Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatic Steatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	3 / 11 (27.27%)
occurrences (all)	1	2	3
Blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Dermatitis Bullous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Erythema Multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Lichenoid Keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nail Discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Nail Dystrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Rash Erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash Macular			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Skin Disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bladder Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Calculus Bladder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urge Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	3 / 11 (27.27%)
occurrences (all)	1	2	4
Bone Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Groin Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mobility Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle Tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Neck Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pain in Extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Polyarthritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Citrobacter Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	2
Cystitis Escherichia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Epididymitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fungal Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Herpes Simplex			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Herpes Zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lung Abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	1	4	0
Oral Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash Pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Skin Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Tooth Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 11 (9.09%)
occurrences (all)	0	1	1

Urinary Tract Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences (all)	1	0	2
Vaginal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Viral Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	2 / 3 (66.67%)	3 / 10 (30.00%)	8 / 11 (72.73%)
occurrences (all)	3	3	12
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fluid Overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	2 / 11 (18.18%)
occurrences (all)	2	0	3
Hypermagnesaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	1 / 11 (9.09%)
occurrences (all)	0	3	2
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 3 (66.67%)	3 / 10 (30.00%)	3 / 11 (27.27%)
occurrences (all)	2	3	6
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	2 / 11 (18.18%)
occurrences (all)	1	4	2
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	7
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency			

subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose-escalation Part: Enapotamab Vedotin 2.4 mg/kg 1Q3W	Dose-escalation Part: Enapotamab Vedotin 0.6 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 0.8 mg/kg 3Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jugular Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular Compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application Site Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Axillary Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Condition Aggravated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Face Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	3	1	2
Feeling Abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait Disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hernia Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical Device Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Mucosal Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Non-cardiac Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Physical Deconditioning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Soft Tissue Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temperature Intolerance			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaccination Site Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Perineal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal Discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Vulvovaginal Dryness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal Pain			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Adductor Vocal Cord Weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	1
Dysaesthesia Pharynx			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Dyspnoea Exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Paranasal Sinus Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleuritic Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia Aspiration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vasomotor Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional State			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Depressed Mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, Olfactory			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mental Status Changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	2
Amylase Increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	4	0	2
Blood Albumin Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Bilirubin Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Iron Decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Magnesium Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Phosphorus Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Urea Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breath Sounds Abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-reactive Protein Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase Increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Glomerular Filtration Rate Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase Increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 Test Positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcus Test Positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin T Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Weight Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White Blood Cells Urine Positive			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Compression Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lumbar Vertebral Fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post Procedural Swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Radiation Necrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tendon Rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pericardial Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular Extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amputation Stump Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Autonomic Nervous System Imbalance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Autonomic Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed Level of Consciousness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mononeuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Monoplegia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neuropathy Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paresis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal Cord Compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Anaemia Macrocytic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia of Chronic Disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Febrile Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	6	0	0
Normocytic Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Borderline Glaucoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Eye Irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Trichomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous Floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Abdominal Pain			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Ascites			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	2 / 3 (66.67%)
occurrences (all)	1	2	3
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Dry Mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Duodenogastric Reflux			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epigastric Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastric Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiatus Hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia Teeth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Impaired Gastric Emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intestinal Obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 3 (100.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	7	0	2
Neutropenic Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary Duct Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 3 (100.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	6	1	0
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic Steatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	3 / 3 (100.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Bullous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema Multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lichenoid Keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail Discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail Dystrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash Erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Macular			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bladder Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Calculus Bladder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urge Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Urinary Retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mobility Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscle Tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Citrobacter Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis Escherichia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Epididymitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Herpes Simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung Abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urinary Tract Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	5	0	0
Vaginal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	5	1	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fluid Overload			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Hypophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose-escalation Part: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Dose-escalation Part: Enapotamab Vedotin 1.2 mg/kg 3Q4W	Expansion Part Cohort 1: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	3 / 3 (100.00%)	22 / 22 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	3

Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Jugular Vein Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Orthostatic Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular Compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application Site Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Axillary Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Chest Pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Condition Aggravated			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Face Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 6 (83.33%)	2 / 3 (66.67%)	13 / 22 (59.09%)
occurrences (all)	14	3	15
Feeling Abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gait Disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Hernia Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Influenza Like Illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Localised Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Medical Device Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Non-cardiac Chest Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Oedema Peripheral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Physical Deconditioning			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	5 / 22 (22.73%)
occurrences (all)	2	0	6
Soft Tissue Inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Temperature Intolerance			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vaccination Site Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Breast Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Perineal Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vaginal Discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Dryness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adductor Vocal Cord Weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Dysaesthesia Pharynx			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	5 / 22 (22.73%)
occurrences (all)	0	0	5
Dyspnoea Exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypoventilation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasal Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Paranasal Sinus Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Pleuritic Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pneumonia Aspiration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pulmonary Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pulmonary Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Sinus Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinus Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vasomotor Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Confusional State			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Depressed Mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hallucination, Olfactory			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mental Status Changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	6 / 22 (27.27%)
occurrences (all)	0	1	6
Amylase Increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	6 / 22 (27.27%)
occurrences (all)	2	1	6
Blood Albumin Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	4 / 22 (18.18%)
occurrences (all)	0	1	4
Blood Bilirubin Increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	5	0	1
Blood Iron Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Magnesium Decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Blood Phosphorus Decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Blood Urea Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Breath Sounds Abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
C-reactive Protein Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase Increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	2 / 22 (9.09%)
occurrences (all)	1	1	2
Glomerular Filtration Rate Decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Lipase Increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	1	0	5
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Platelet Count Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 Test Positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Staphylococcus Test Positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Troponin T Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Troponin Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	5 / 22 (22.73%)
occurrences (all)	2	0	5

Weight Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Compression Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Infusion Related Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lip Injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lumbar Vertebral Fracture			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Post Procedural Swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Radiation Necrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tendon Rupture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Pericardial Effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Supraventricular Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Ventricular Extrasystoles			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amputation Stump Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Autonomic Nervous System Imbalance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Autonomic Neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Balance Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Depressed Level of Consciousness			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Hyperaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolic Encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mononeuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Monoplegia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neuropathy Peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	2	0	2
Paresis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Peripheral Motor Neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	9 / 22 (40.91%)
occurrences (all)	2	0	14
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Spinal Cord Compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Taste Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 6 (50.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	10	0	6
Anaemia Macrocytic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Anaemia of Chronic Disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Febrile Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	9
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	3 / 22 (13.64%)
occurrences (all)	2	1	6
Normocytic Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Borderline Glaucoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye Irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

Trichomegaly			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	3
Visual Impairment			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Vitreous Floaters			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Abdominal Distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	2 / 6 (33.33%)	1 / 3 (33.33%)	4 / 22 (18.18%)
occurrences (all)	3	1	7
Abdominal Pain Lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Colitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	4 / 6 (66.67%)	0 / 3 (0.00%)	7 / 22 (31.82%)
occurrences (all)	8	0	9
Diarrhoea			
subjects affected / exposed	4 / 6 (66.67%)	1 / 3 (33.33%)	5 / 22 (22.73%)
occurrences (all)	9	1	7
Dry Mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
Duodenogastric Reflux			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Dysphagia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Epigastric Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Eructation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastric Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Gingival Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Gingival Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hiatus Hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia Teeth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Impaired Gastric Emptying			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Intestinal Obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 6 (66.67%)	2 / 3 (66.67%)	14 / 22 (63.64%)
occurrences (all)	6	2	18
Neutropenic Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Retching			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Salivary Duct Inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	6 / 22 (27.27%)
occurrences (all)	3	3	6
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hepatic Failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hepatic Steatosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Jaundice			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	2	0	4
Blister			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis Bullous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Erythema Multiforme			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lichenoid Keratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nail Discolouration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nail Dystrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Onychoclasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Psoriasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash Erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Rash Macular			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin Disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin Mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin Reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bladder Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Calculus Bladder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urge Incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	2	0	6
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Back Pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	6
Bone Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	4
Groin Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Limb Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mobility Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	4 / 22 (18.18%)
occurrences (all)	0	0	5
Muscle Tightness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	2 / 22 (9.09%)
occurrences (all)	3	0	2
Neck Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	3
Polyarthritis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Candida Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Citrobacter Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Cystitis Escherichia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Epididymitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fungal Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes Simplex			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Lung Abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Pyuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rash Pustular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Urinary Tract Candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	2 / 6 (33.33%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	3	0	4
Vaginal Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Viral Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	3 / 6 (50.00%)	1 / 3 (33.33%)	8 / 22 (36.36%)
occurrences (all)	4	1	10
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Fluid Overload			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	4
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 3 (66.67%)	2 / 22 (9.09%)
occurrences (all)	0	2	2
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Hypernatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	3 / 22 (13.64%)
occurrences (all)	1	1	3
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	4 / 22 (18.18%)
occurrences (all)	0	2	4
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	7 / 22 (31.82%)
occurrences (all)	1	1	8
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 3 (33.33%)	3 / 22 (13.64%)
occurrences (all)	1	1	3
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
Hypophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 3 (33.33%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
Iron Deficiency			

subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 3 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Expansion Part Cohort 3: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 4: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 5: Enapotamab Vedotin 2.2 mg/kg 1Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	24 / 25 (96.00%)	25 / 25 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Hypertension			
subjects affected / exposed	4 / 16 (25.00%)	1 / 25 (4.00%)	3 / 25 (12.00%)
occurrences (all)	4	1	9

Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	3 / 25 (12.00%)
occurrences (all)	0	2	3
Jugular Vein Thrombosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Orthostatic Hypotension			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Thrombophlebitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vascular Compression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application Site Reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Axillary Pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Chest Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Chest Pain			

subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	1 / 16 (6.25%)	2 / 25 (8.00%)	2 / 25 (8.00%)
occurrences (all)	2	2	5
Condition Aggravated			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Face Oedema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	8 / 16 (50.00%)	16 / 25 (64.00%)	14 / 25 (56.00%)
occurrences (all)	9	22	22
Feeling Abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gait Disturbance			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Hernia Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infusion Site Reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Localised Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Medical Device Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Non-cardiac Chest Pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	0	3	3
Pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	2	0	2
Peripheral Swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Physical Deconditioning			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	3 / 16 (18.75%)	5 / 25 (20.00%)	0 / 25 (0.00%)
occurrences (all)	4	6	0
Soft Tissue Inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Temperature Intolerance			

subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Tenderness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Vaccination Site Reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Breast Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Perineal Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vaginal Discharge			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Dryness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adductor Vocal Cord Weakness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 16 (0.00%)	4 / 25 (16.00%)	3 / 25 (12.00%)
occurrences (all)	0	4	3
Dysaesthesia Pharynx			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 16 (6.25%)	3 / 25 (12.00%)	1 / 25 (4.00%)
occurrences (all)	1	3	1
Dyspnoea			
subjects affected / exposed	0 / 16 (0.00%)	4 / 25 (16.00%)	2 / 25 (8.00%)
occurrences (all)	0	4	2
Dyspnoea Exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Hypoventilation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Nasal Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Paranasal Sinus Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pleuritic Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Pneumonia Aspiration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Productive Cough			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Pulmonary Embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pulmonary Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Sinus Congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Sinus Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Sinus Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Vasomotor Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Confusional State			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Depressed Mood			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	2 / 16 (12.50%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	2	1	1
Hallucination			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hallucination, Olfactory			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	2 / 25 (8.00%)
occurrences (all)	0	3	3
Irritability			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Mental Status Changes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 16 (18.75%)	4 / 25 (16.00%)	6 / 25 (24.00%)
occurrences (all)	4	6	9
Amylase Increased			

subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	2 / 16 (12.50%)	3 / 25 (12.00%)	6 / 25 (24.00%)
occurrences (all)	2	4	10
Blood Albumin Decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Blood Bilirubin Increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Blood Creatinine Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Iron Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Blood Magnesium Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Phosphorus Decreased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood Urea Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Breath Sounds Abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
C-reactive Protein Increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase Increased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Glomerular Filtration Rate Decreased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lipase Increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Platelet Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
SARS-CoV-2 Test Positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Staphylococcus Test Positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Troponin T Increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Troponin Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	1 / 16 (6.25%)	3 / 25 (12.00%)	3 / 25 (12.00%)
occurrences (all)	1	3	3

Weight Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Compression Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 16 (6.25%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Infusion Related Reaction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lip Injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lumbar Vertebral Fracture			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Post Procedural Swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Radiation Necrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tendon Rupture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Wrist Fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1

Pericardial Effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 16 (6.25%)	2 / 25 (8.00%)	3 / 25 (12.00%)
occurrences (all)	1	2	4
Ventricular Extrasystoles			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amputation Stump Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Autonomic Nervous System Imbalance			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Autonomic Neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Balance Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	2
Cognitive Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Depressed Level of Consciousness			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	3 / 16 (18.75%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	3	0	0
Dysaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	5 / 25 (20.00%)
occurrences (all)	1	1	5
Headache			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	4 / 25 (16.00%)
occurrences (all)	0	2	5
Hyperaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Lethargy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Metabolic Encephalopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Mononeuropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Monoplegia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	3
Neuropathy Peripheral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	2
Neurotoxicity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Paresis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Parosmia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Peripheral Motor Neuropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	1 / 16 (6.25%)	3 / 25 (12.00%)	1 / 25 (4.00%)
occurrences (all)	1	5	1
Peripheral Sensory Neuropathy			
subjects affected / exposed	2 / 16 (12.50%)	4 / 25 (16.00%)	7 / 25 (28.00%)
occurrences (all)	3	4	11
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Presyncope			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Restless Legs Syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Spinal Cord Compression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Taste Disorder			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 16 (12.50%)	3 / 25 (12.00%)	4 / 25 (16.00%)
occurrences (all)	2	6	6
Anaemia Macrocytic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Anaemia of Chronic Disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Febrile Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	3 / 25 (12.00%)	0 / 25 (0.00%)
occurrences (all)	0	3	0
Leukocytosis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Leukopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 16 (12.50%)	5 / 25 (20.00%)	7 / 25 (28.00%)
occurrences (all)	2	11	13
Normocytic Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Borderline Glaucoma			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Eye Irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Photophobia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Trichomegaly			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vitreous Floaters			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	3 / 25 (12.00%)	0 / 25 (0.00%)
occurrences (all)	0	3	0
Abdominal Distension			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Abdominal Pain			
subjects affected / exposed	4 / 16 (25.00%)	8 / 25 (32.00%)	5 / 25 (20.00%)
occurrences (all)	6	8	5
Abdominal Pain Lower			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	4 / 25 (16.00%)
occurrences (all)	0	1	4
Ascites			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Colitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	5 / 16 (31.25%)	12 / 25 (48.00%)	13 / 25 (52.00%)
occurrences (all)	9	15	16
Diarrhoea			
subjects affected / exposed	8 / 16 (50.00%)	10 / 25 (40.00%)	10 / 25 (40.00%)
occurrences (all)	10	13	21
Dry Mouth			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	3 / 25 (12.00%)
occurrences (all)	0	1	3
Duodenogastric Reflux			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	1 / 16 (6.25%)	3 / 25 (12.00%)	4 / 25 (16.00%)
occurrences (all)	1	3	4
Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Epigastric Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Gastric Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Gingival Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gingival Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Hiatus Hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia Teeth			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Impaired Gastric Emptying			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Intestinal Obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	10 / 16 (62.50%)	11 / 25 (44.00%)	15 / 25 (60.00%)
occurrences (all)	12	12	20
Neutropenic Colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Salivary Duct Inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 16 (18.75%)	4 / 25 (16.00%)	6 / 25 (24.00%)
occurrences (all)	3	4	10
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hepatic Failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hepatic Steatosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0

Jaundice			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	5 / 16 (31.25%)	7 / 25 (28.00%)	8 / 25 (32.00%)
occurrences (all)	5	7	9
Blister			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dermatitis Bullous			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dermatitis Contact			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Ecchymosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Erythema Multiforme			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lichenoid Keratosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nail Discolouration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nail Dystrophy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 16 (18.75%)	4 / 25 (16.00%)	1 / 25 (4.00%)
occurrences (all)	4	4	2
Psoriasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	3
Rash Erythematous			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Rash Macular			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-papular			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Rash Pruritic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Skin Disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Skin Irritation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin Mass			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Skin Reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Bladder Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Calculus Bladder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Polyuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urge Incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 16 (6.25%)	3 / 25 (12.00%)	7 / 25 (28.00%)
occurrences (all)	1	3	9
Arthritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 16 (0.00%)	4 / 25 (16.00%)	1 / 25 (4.00%)
occurrences (all)	0	4	1
Bone Pain			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Bursitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Fistula			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Flank Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Groin Pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Mobility Decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	2
Muscle Tightness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Muscular Weakness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Musculoskeletal Discomfort			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	4 / 16 (25.00%)	4 / 25 (16.00%)	5 / 25 (20.00%)
occurrences (all)	6	5	6
Neck Pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Pain in Extremity			
subjects affected / exposed	5 / 16 (31.25%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	6	0	3
Polyarthritis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Bronchiolitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Citrobacter Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Cystitis Escherichia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Epididymitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Escherichia Urinary Tract Infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Eye Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Fungal Oesophagitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Herpes Simplex			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Lung Abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	2 / 25 (8.00%)
occurrences (all)	0	1	2
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	1	0	2
Pyuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Rash Pustular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Skin Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Urinary Tract Candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Urinary Tract Infection			
subjects affected / exposed	1 / 16 (6.25%)	3 / 25 (12.00%)	1 / 25 (4.00%)
occurrences (all)	1	3	1
Vaginal Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Viral Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	8 / 16 (50.00%)	5 / 25 (20.00%)	8 / 25 (32.00%)
occurrences (all)	8	6	11
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Fluid Overload			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 25 (8.00%)	0 / 25 (0.00%)
occurrences (all)	0	4	0
Hyperkalaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Hypertriglyceridaemia			
subjects affected / exposed	2 / 16 (12.50%)	2 / 25 (8.00%)	1 / 25 (4.00%)
occurrences (all)	6	4	2
Hyperuricaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Hypoglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	2 / 16 (12.50%)	2 / 25 (8.00%)	3 / 25 (12.00%)
occurrences (all)	2	4	3
Hypomagnesaemia			
subjects affected / exposed	1 / 16 (6.25%)	3 / 25 (12.00%)	0 / 25 (0.00%)
occurrences (all)	1	4	0
Hyponatraemia			
subjects affected / exposed	0 / 16 (0.00%)	3 / 25 (12.00%)	1 / 25 (4.00%)
occurrences (all)	0	4	1
Hypophagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	3
Iron Deficiency			

subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Vitamin D Deficiency			
subjects affected / exposed	0 / 16 (0.00%)	1 / 25 (4.00%)	0 / 25 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Expansion Part Cohort 6: Enapotamab Vedotin 1.0 mg/kg 3Q4W	Expansion Part Cohort 7: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 8: Enapotamab Vedotin 1.0 mg/kg 3Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 44 (100.00%)	25 / 25 (100.00%)	23 / 26 (88.46%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Hot Flush			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Hypertension			
subjects affected / exposed	0 / 44 (0.00%)	4 / 25 (16.00%)	1 / 26 (3.85%)
occurrences (all)	0	4	1

Hypotension			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Jugular Vein Thrombosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Orthostatic Hypotension			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
Thrombophlebitis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vascular Compression			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application Site Reaction			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	2 / 26 (7.69%)
occurrences (all)	1	1	2
Axillary Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Chest Pain			

subjects affected / exposed	2 / 44 (4.55%)	4 / 25 (16.00%)	2 / 26 (7.69%)
occurrences (all)	3	5	2
Chills			
subjects affected / exposed	4 / 44 (9.09%)	2 / 25 (8.00%)	5 / 26 (19.23%)
occurrences (all)	4	2	5
Condition Aggravated			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Face Oedema			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	23 / 44 (52.27%)	13 / 25 (52.00%)	13 / 26 (50.00%)
occurrences (all)	31	17	14
Feeling Abnormal			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	3	0	0
Gait Disturbance			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Hernia Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Infusion Site Reaction			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Localised Oedema			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 44 (0.00%)	2 / 25 (8.00%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
Medical Device Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Nodule			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Non-cardiac Chest Pain			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	2	0	2
Oedema			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Oedema Peripheral			
subjects affected / exposed	3 / 44 (6.82%)	2 / 25 (8.00%)	1 / 26 (3.85%)
occurrences (all)	3	2	1
Pain			
subjects affected / exposed	3 / 44 (6.82%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	3	0	0
Peripheral Swelling			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Physical Deconditioning			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	5 / 44 (11.36%)	1 / 25 (4.00%)	2 / 26 (7.69%)
occurrences (all)	6	2	3
Soft Tissue Inflammation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Temperature Intolerance			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vaccination Site Reaction			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Xerosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Breast Pain			
subjects affected / exposed	0 / 44 (0.00%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Dysmenorrhoea			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Perineal Pain			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Vaginal Discharge			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Vaginal Haemorrhage			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal Dryness			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pain			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adductor Vocal Cord Weakness			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Aspiration			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	5 / 44 (11.36%)	2 / 25 (8.00%)	3 / 26 (11.54%)
occurrences (all)	6	2	10
Dysaesthesia Pharynx			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			
subjects affected / exposed	4 / 44 (9.09%)	2 / 25 (8.00%)	10 / 26 (38.46%)
occurrences (all)	4	3	12
Dyspnoea Exertional			
subjects affected / exposed	1 / 44 (2.27%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
Epistaxis			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Hypoventilation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Nasal Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	3
Paranasal Sinus Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pleural Effusion			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Pleuritic Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Pneumonia Aspiration			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Pulmonary Embolism			
subjects affected / exposed	2 / 44 (4.55%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences (all)	2	1	1
Pulmonary Haemorrhage			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	3
Sinus Congestion			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Sinus Disorder			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Sinus Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vasomotor Rhinitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	2
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	3 / 44 (6.82%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences (all)	3	1	1
Confusional State			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Delirium			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0

Depressed Mood			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	2	0	2
Hallucination			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hallucination, Olfactory			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Hallucination, Visual			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	5 / 44 (11.36%)	5 / 25 (20.00%)	7 / 26 (26.92%)
occurrences (all)	5	5	7
Irritability			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Mental Status Changes			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 44 (6.82%)	5 / 25 (20.00%)	2 / 26 (7.69%)
occurrences (all)	3	6	2
Amylase Increased			

subjects affected / exposed	2 / 44 (4.55%)	3 / 25 (12.00%)	0 / 26 (0.00%)
occurrences (all)	2	4	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	3 / 44 (6.82%)	6 / 25 (24.00%)	1 / 26 (3.85%)
occurrences (all)	3	7	1
Blood Albumin Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
Blood Bilirubin Increased			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	4	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Creatinine Increased			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
Blood Iron Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Blood Magnesium Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Phosphorus Decreased			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Sodium Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Blood Urea Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Breath Sounds Abnormal			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
C-reactive Protein Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase Increased			
subjects affected / exposed	1 / 44 (2.27%)	6 / 25 (24.00%)	3 / 26 (11.54%)
occurrences (all)	1	6	3
Glomerular Filtration Rate Decreased			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
International Normalised Ratio Increased			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	4	0	0
Lipase Increased			
subjects affected / exposed	2 / 44 (4.55%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	2	2	0
Lymphocyte Count Decreased			
subjects affected / exposed	2 / 44 (4.55%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	4	3	0
Neutrophil Count Decreased			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Platelet Count Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 Test Positive			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Staphylococcus Test Positive			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Troponin T Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Troponin Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	8 / 44 (18.18%)	0 / 25 (0.00%)	5 / 26 (19.23%)
occurrences (all)	8	0	5

Weight Increased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences (all)	3	1	2
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Compression Fracture			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	2
Contusion			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Infusion Related Reaction			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Ligament Sprain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Lip Injury			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Lumbar Vertebral Fracture			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Post Procedural Swelling			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Procedural Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Radiation Necrosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Tendon Rupture			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Thermal Burn			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0

Pericardial Effusion			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	3 / 44 (6.82%)	1 / 25 (4.00%)	2 / 26 (7.69%)
occurrences (all)	3	1	2
Ventricular Extrasystoles			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amputation Stump Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Autonomic Nervous System Imbalance			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Autonomic Neuropathy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Balance Disorder			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Cognitive Disorder			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Depressed Level of Consciousness			

subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Disturbance in Attention			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Dizziness			
subjects affected / exposed	3 / 44 (6.82%)	0 / 25 (0.00%)	4 / 26 (15.38%)
occurrences (all)	4	0	5
Dysaesthesia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	6 / 44 (13.64%)	0 / 25 (0.00%)	5 / 26 (19.23%)
occurrences (all)	7	0	5
Headache			
subjects affected / exposed	5 / 44 (11.36%)	5 / 25 (20.00%)	4 / 26 (15.38%)
occurrences (all)	11	6	10
Hyperaesthesia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	2 / 44 (4.55%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	2	2	0
Metabolic Encephalopathy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Mononeuropathy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Monoplegia			

subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Neuropathy Peripheral			
subjects affected / exposed	5 / 44 (11.36%)	0 / 25 (0.00%)	3 / 26 (11.54%)
occurrences (all)	6	0	3
Neurotoxicity			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	3	0	1
Paresis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Peripheral Motor Neuropathy			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	3 / 44 (6.82%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	3	1	0
Peripheral Sensory Neuropathy			
subjects affected / exposed	11 / 44 (25.00%)	6 / 25 (24.00%)	7 / 26 (26.92%)
occurrences (all)	14	6	7
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Presyncope			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
subjects affected / exposed	1 / 44 (2.27%)	5 / 25 (20.00%)	0 / 26 (0.00%)
occurrences (all)	1	5	0
Seizure			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Spinal Cord Compression			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Taste Disorder			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Tremor			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 44 (13.64%)	3 / 25 (12.00%)	4 / 26 (15.38%)
occurrences (all)	8	3	5
Anaemia Macrocytic			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Anaemia of Chronic Disease			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1

Febrile Neutropenia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 44 (2.27%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	2	2	0
Lymphadenopathy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 44 (0.00%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Neutropenia			
subjects affected / exposed	2 / 44 (4.55%)	9 / 25 (36.00%)	0 / 26 (0.00%)
occurrences (all)	3	14	0
Normocytic Anaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Eye disorders			

Blepharitis			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Borderline Glaucoma			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Conjunctival Haemorrhage			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Diplopia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Dry Eye			
subjects affected / exposed	2 / 44 (4.55%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	2	2	0
Eye Irritation			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Eye Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Lacrimation Increased			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Ocular Hyperaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Photopsia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1

Trichomegaly			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
Visual Impairment			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vitreous Floaters			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Abdominal Distension			
subjects affected / exposed	0 / 44 (0.00%)	3 / 25 (12.00%)	2 / 26 (7.69%)
occurrences (all)	0	3	2
Abdominal Pain			
subjects affected / exposed	10 / 44 (22.73%)	9 / 25 (36.00%)	7 / 26 (26.92%)
occurrences (all)	10	13	13
Abdominal Pain Lower			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	2 / 44 (4.55%)	3 / 25 (12.00%)	1 / 26 (3.85%)
occurrences (all)	2	3	1
Ascites			
subjects affected / exposed	2 / 44 (4.55%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Cheilitis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Colitis			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	11 / 44 (25.00%)	7 / 25 (28.00%)	11 / 26 (42.31%)
occurrences (all)	13	9	13
Diarrhoea			
subjects affected / exposed	13 / 44 (29.55%)	9 / 25 (36.00%)	11 / 26 (42.31%)
occurrences (all)	17	10	18
Dry Mouth			
subjects affected / exposed	5 / 44 (11.36%)	2 / 25 (8.00%)	5 / 26 (19.23%)
occurrences (all)	5	3	8
Duodenogastric Reflux			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	2	0	2
Dysphagia			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Epigastric Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Gastric Disorder			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Pain			

subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 44 (0.00%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
Gingival Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Gingival Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
Hiatus Hernia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia Teeth			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Impaired Gastric Emptying			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Intestinal Obstruction			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	13 / 44 (29.55%)	15 / 25 (60.00%)	11 / 26 (42.31%)
occurrences (all)	19	22	16
Neutropenic Colitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	2
Proctalgia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	2
Salivary Duct Inflammation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	2	0	1
Toothache			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	9 / 44 (20.45%)	7 / 25 (28.00%)	7 / 26 (26.92%)
occurrences (all)	15	8	16
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Cholangitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hepatic Failure			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hepatic Steatosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hepatitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Jaundice			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	3 / 44 (6.82%)	9 / 25 (36.00%)	6 / 26 (23.08%)
occurrences (all)	3	9	6
Blister			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Dermatitis Allergic			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Dermatitis Bullous			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Dermatitis Contact			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	2	0	2
Ecchymosis			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Erythema Multiforme			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hair Texture Abnormal			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Lichenoid Keratosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Nail Discolouration			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Nail Disorder			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Nail Dystrophy			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
Onychoclasis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	6 / 44 (13.64%)	3 / 25 (12.00%)	3 / 26 (11.54%)
occurrences (all)	7	4	3
Psoriasis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	5 / 44 (11.36%)	2 / 25 (8.00%)	3 / 26 (11.54%)
occurrences (all)	5	2	5
Rash Erythematous			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rash Macular			

subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Rash Maculo-papular			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin Disorder			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin Hyperpigmentation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Skin Mass			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Skin Reaction			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 44 (2.27%)	2 / 25 (8.00%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
Bladder Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Calculus Bladder			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Dysuria			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Hypertonic Bladder			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Urge Incontinence			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Urinary Incontinence			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 44 (13.64%)	2 / 25 (8.00%)	5 / 26 (19.23%)
occurrences (all)	6	3	5
Arthritis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	6 / 44 (13.64%)	2 / 25 (8.00%)	3 / 26 (11.54%)
occurrences (all)	6	2	4
Bone Pain			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Bursitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Fistula			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Flank Pain			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	2	0	2
Groin Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Limb Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Mobility Decreased			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Muscle Tightness			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	4 / 44 (9.09%)	3 / 25 (12.00%)	3 / 26 (11.54%)
occurrences (all)	4	3	3
Neck Pain			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Pain in Extremity			
subjects affected / exposed	1 / 44 (2.27%)	2 / 25 (8.00%)	2 / 26 (7.69%)
occurrences (all)	1	2	2
Polyarthritis			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Spinal Pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Citrobacter Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Cystitis Escherichia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Epididymitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Fungal Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Fungal Oesophagitis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis Viral			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Herpes Simplex			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Infection			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Lung Abscess			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Oral Candidiasis			
subjects affected / exposed	2 / 44 (4.55%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	3 / 26 (11.54%)
occurrences (all)	1	1	6
Pyuria			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Rash Pustular			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Skin Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Tooth Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Urinary Tract Candidiasis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 44 (2.27%)	1 / 25 (4.00%)	1 / 26 (3.85%)
occurrences (all)	5	1	1
Vaginal Infection			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Viral Infection			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	14 / 44 (31.82%)	7 / 25 (28.00%)	12 / 26 (46.15%)
occurrences (all)	14	7	16
Dehydration			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Fluid Overload			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 44 (2.27%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 44 (2.27%)	2 / 25 (8.00%)	2 / 26 (7.69%)
occurrences (all)	1	2	3
Hyperkalaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 44 (0.00%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 44 (4.55%)	1 / 25 (4.00%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
Hypocalcaemia			
subjects affected / exposed	2 / 44 (4.55%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	3 / 44 (6.82%)	2 / 25 (8.00%)	3 / 26 (11.54%)
occurrences (all)	5	2	5
Hypomagnesaemia			
subjects affected / exposed	3 / 44 (6.82%)	2 / 25 (8.00%)	3 / 26 (11.54%)
occurrences (all)	3	2	6
Hyponatraemia			
subjects affected / exposed	2 / 44 (4.55%)	2 / 25 (8.00%)	4 / 26 (15.38%)
occurrences (all)	2	2	6
Hypophagia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	3 / 44 (6.82%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	3	0	0
Iron Deficiency			

subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Vitamin D Deficiency			
subjects affected / exposed	0 / 44 (0.00%)	0 / 25 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Expansion Part Cohort 2: Enapotamab Vedotin 2.2 mg/kg 1Q3W	Expansion Part Cohort 2: Enapotamab Vedotin 1.8 mg/kg 1Q3W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 56 (100.00%)	20 / 20 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	3	
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hot Flush			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences (all)	3	0	

Hypotension			
subjects affected / exposed	7 / 56 (12.50%)	0 / 20 (0.00%)	
occurrences (all)	7	0	
Jugular Vein Thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Orthostatic Hypotension			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Thrombophlebitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Thrombophlebitis Superficial			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Thrombosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vascular Compression			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Application Site Reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Axillary Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Chest Discomfort			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Chest Pain			

subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Chills			
subjects affected / exposed	3 / 56 (5.36%)	2 / 20 (10.00%)	
occurrences (all)	3	2	
Condition Aggravated			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Face Oedema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	31 / 56 (55.36%)	11 / 20 (55.00%)	
occurrences (all)	37	13	
Feeling Abnormal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Gait Disturbance			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	2	
Hernia Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Inflammation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Influenza Like Illness			
subjects affected / exposed	2 / 56 (3.57%)	1 / 20 (5.00%)	
occurrences (all)	2	2	
Infusion Site Reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Localised Oedema			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Malaise			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Medical Device Discomfort			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Mucosal Inflammation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Nodule			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Non-cardiac Chest Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Oedema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Oedema Peripheral			
subjects affected / exposed	2 / 56 (3.57%)	4 / 20 (20.00%)	
occurrences (all)	3	6	
Pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Peripheral Swelling			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Physical Deconditioning			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	7 / 56 (12.50%)	3 / 20 (15.00%)	
occurrences (all)	7	4	
Soft Tissue Inflammation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Temperature Intolerance			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Tenderness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vaccination Site Reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Xerosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Breast Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dysmenorrhoea			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Perineal Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vaginal Discharge			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vaginal Haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal Dryness			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Vulvovaginal Pain			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Adductor Vocal Cord Weakness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Aspiration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	5 / 56 (8.93%)	2 / 20 (10.00%)	
occurrences (all)	5	3	
Dysaesthesia Pharynx			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Dysphonia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Dyspnoea			
subjects affected / exposed	6 / 56 (10.71%)	6 / 20 (30.00%)	
occurrences (all)	8	7	
Dyspnoea Exertional			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Epistaxis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hypoventilation			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Hypoxia			

subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)		
occurrences (all)	1	0		
Nasal Congestion				
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)		
occurrences (all)	0	1		
Nasal Discomfort				
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)		
occurrences (all)	0	0		
Oropharyngeal Pain				
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)		
occurrences (all)	2	0		
Paranasal Sinus Discomfort				
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)		
occurrences (all)	1	0		
Pleural Effusion				
subjects affected / exposed	2 / 56 (3.57%)	1 / 20 (5.00%)		
occurrences (all)	2	1		
Pleuritic Pain				
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)		
occurrences (all)	0	0		
Pneumonia Aspiration				
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)		
occurrences (all)	0	0		
Pneumonitis				
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)		
occurrences (all)	1	1		
Productive Cough				
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)		
occurrences (all)	3	1		
Pulmonary Embolism				
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)		
occurrences (all)	1	1		
Pulmonary Haemorrhage				
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)		
occurrences (all)	1	0		
Rhinitis Allergic				

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Sinus Congestion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Sinus Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Sinus Pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Upper-airway Cough Syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vasomotor Rhinitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Anxiety			
subjects affected / exposed	3 / 56 (5.36%)	2 / 20 (10.00%)	
occurrences (all)	3	2	
Confusional State			
subjects affected / exposed	2 / 56 (3.57%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Delirium			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

Depressed Mood			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hallucination			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hallucination, Olfactory			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hallucination, Visual			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	8 / 56 (14.29%)	3 / 20 (15.00%)	
occurrences (all)	8	3	
Irritability			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Mental Status Changes			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Restlessness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Alanine Aminotransferase Increased			
subjects affected / exposed	10 / 56 (17.86%)	0 / 20 (0.00%)	
occurrences (all)	11	0	
Amylase Increased			

subjects affected / exposed	3 / 56 (5.36%)	2 / 20 (10.00%)	
occurrences (all)	6	2	
Aspartate Aminotransferase Increased			
subjects affected / exposed	13 / 56 (23.21%)	0 / 20 (0.00%)	
occurrences (all)	17	0	
Blood Albumin Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	6 / 56 (10.71%)	0 / 20 (0.00%)	
occurrences (all)	6	0	
Blood Bilirubin Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Blood Cholesterol Increased			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	3	0	
Blood Creatinine Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Blood Iron Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood Magnesium Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood Phosphorus Decreased			

subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Blood Potassium Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Blood Sodium Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood Thyroid Stimulating Hormone Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood Triglycerides Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Blood Urea Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Brain Natriuretic Peptide Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Breath Sounds Abnormal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
C-reactive Protein Increased			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences (all)	6	0	
Electrocardiogram QT Prolonged			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Gamma-glutamyltransferase Increased			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences (all)	3	0	
Glomerular Filtration Rate Decreased			

subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
International Normalised Ratio Increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Lipase Increased			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences (all)	4	1	
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Neutrophil Count Decreased			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Platelet Count Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
SARS-CoV-2 Test Positive			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Staphylococcus Test Positive			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Troponin T Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Troponin Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vitamin B12 Decreased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Weight Decreased			
subjects affected / exposed	13 / 56 (23.21%)	2 / 20 (10.00%)	
occurrences (all)	13	2	

Weight Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Clavicle Fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Compression Fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Infusion Related Reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Injury			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Ligament Sprain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Lip Injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Lumbar Vertebral Fracture			

subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Overdose			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Post Procedural Discomfort			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Post Procedural Swelling			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Procedural Pain			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences (all)	3	0	
Radiation Necrosis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Tendon Rupture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Thermal Burn			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Wound			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Wrist Fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Palpitations			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

Pericardial Effusion			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Sinus Tachycardia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Supraventricular Tachycardia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	4 / 56 (7.14%)	0 / 20 (0.00%)	
occurrences (all)	4	0	
Ventricular Extrasystoles			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Amputation Stump Pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Autonomic Nervous System Imbalance			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Autonomic Neuropathy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Balance Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cognitive Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Depressed Level of Consciousness			

subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Disturbance in Attention			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	5 / 56 (8.93%)	3 / 20 (15.00%)	
occurrences (all)	5	3	
Dysaesthesia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Headache			
subjects affected / exposed	5 / 56 (8.93%)	4 / 20 (20.00%)	
occurrences (all)	7	4	
Hyperaesthesia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Lethargy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Metabolic Encephalopathy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Migraine			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Mononeuropathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Monoplegia			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Neuralgia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Neuropathy Peripheral			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Neurotoxicity			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Paresis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Parosmia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Peripheral Motor Neuropathy			
subjects affected / exposed	4 / 56 (7.14%)	0 / 20 (0.00%)	
occurrences (all)	4	0	
Peripheral Sensorimotor Neuropathy			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Peripheral Sensory Neuropathy			
subjects affected / exposed	11 / 56 (19.64%)	3 / 20 (15.00%)	
occurrences (all)	11	3	
Peroneal Nerve Palsy			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Polyneuropathy			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	2	
Presyncope			

subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pyramidal Tract Syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Restless Legs Syndrome			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Seizure			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Spinal Cord Compression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Taste Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 56 (19.64%)	3 / 20 (15.00%)	
occurrences (all)	14	3	
Anaemia Macrocytic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Anaemia of Chronic Disease			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Coagulopathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

Febrile Neutropenia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Leukocytosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Lymphadenopathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	7 / 56 (12.50%)	3 / 20 (15.00%)	
occurrences (all)	9	5	
Normocytic Anaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Borderline Glaucoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cataract			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Diplopia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dry Eye			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	2	3	
Eye Irritation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Eye Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Lacrimation Increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Ocular Hyperaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Photophobia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Photopsia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

Trichomegaly			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Vision Blurred			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	2	
Visual Impairment			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Vitreous Floaters			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Abdominal Distension			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Abdominal Pain			
subjects affected / exposed	11 / 56 (19.64%)	3 / 20 (15.00%)	
occurrences (all)	14	3	
Abdominal Pain Lower			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Abdominal Pain Upper			
subjects affected / exposed	4 / 56 (7.14%)	1 / 20 (5.00%)	
occurrences (all)	4	1	
Ascites			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cheilitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Colitis			

subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Constipation			
subjects affected / exposed	31 / 56 (55.36%)	9 / 20 (45.00%)	
occurrences (all)	39	9	
Diarrhoea			
subjects affected / exposed	20 / 56 (35.71%)	6 / 20 (30.00%)	
occurrences (all)	28	6	
Dry Mouth			
subjects affected / exposed	2 / 56 (3.57%)	2 / 20 (10.00%)	
occurrences (all)	2	3	
Duodenogastric Reflux			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	2 / 56 (3.57%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Dysphagia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Epigastric Discomfort			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Eructation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Gastric Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Gastrointestinal Pain			

subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	3 / 56 (5.36%)	0 / 20 (0.00%)	
occurrences (all)	3	0	
Gingival Discomfort			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Gingival Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Haematochezia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Haemorrhoids			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hiatus Hernia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hyperaesthesia Teeth			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Impaired Gastric Emptying			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Intestinal Obstruction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	22 / 56 (39.29%)	6 / 20 (30.00%)	
occurrences (all)	30	7	
Neutropenic Colitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Pancreatitis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Proctalgia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Retching			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Salivary Duct Inflammation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Stomatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	15 / 56 (26.79%)	4 / 20 (20.00%)	
occurrences (all)	21	4	
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cholangitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hepatic Failure			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hepatic Steatosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hepatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

Jaundice			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	14 / 56 (25.00%)	2 / 20 (10.00%)	
occurrences (all)	14	2	
Blister			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dermatitis Allergic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dermatitis Bullous			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dermatitis Contact			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Dry Skin			
subjects affected / exposed	2 / 56 (3.57%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Ecchymosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Erythema Multiforme			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hair Texture Abnormal			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Lichenoid Keratosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Nail Discolouration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Nail Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Nail Dystrophy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Night Sweats			
subjects affected / exposed	1 / 56 (1.79%)	2 / 20 (10.00%)	
occurrences (all)	1	3	
Onychoclasis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Pruritus			
subjects affected / exposed	6 / 56 (10.71%)	1 / 20 (5.00%)	
occurrences (all)	7	1	
Psoriasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	6 / 56 (10.71%)	3 / 20 (15.00%)	
occurrences (all)	7	4	
Rash Erythematous			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rash Macular			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rash Maculo-papular			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rash Pruritic			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Skin Disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin Hyperpigmentation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin Irritation			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Skin Lesion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin Mass			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin Reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Bladder Discomfort			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Calculus Bladder			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	

Dysuria			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Haematuria			
subjects affected / exposed	2 / 56 (3.57%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Hydronephrosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypertonic Bladder			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Nocturia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Polyuria			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Proteinuria			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Urge Incontinence			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Urinary Incontinence			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Urinary Retention			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Hyperthyroidism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 56 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	13	2	
Arthritis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Back Pain			
subjects affected / exposed	9 / 56 (16.07%)	1 / 20 (5.00%)	
occurrences (all)	10	1	
Bone Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Bursitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Fistula			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Flank Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Groin Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Joint Range of Motion Decreased			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Limb Discomfort			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Mobility Decreased			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Muscle Spasms			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Muscle Tightness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Muscular Weakness			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal Discomfort			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	4 / 56 (7.14%)	5 / 20 (25.00%)	
occurrences (all)	4	6	
Neck Pain			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Pain in Extremity			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Polyarthritis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Spinal Pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Bronchiolitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
COVID-19			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Candida Infection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Citrobacter Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Cystitis Escherichia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	

Epididymitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Eye Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Fungal Infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Fungal Oesophagitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis Viral			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Herpes Simplex			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Herpes Zoster			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Lung Abscess			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	

Nasopharyngitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Oral Candidiasis			
subjects affected / exposed	5 / 56 (8.93%)	0 / 20 (0.00%)	
occurrences (all)	5	0	
Parainfluenzae Virus Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pyuria			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rash Pustular			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Tooth Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 56 (3.57%)	1 / 20 (5.00%)	
occurrences (all)	2	1	

Urinary Tract Candidiasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Urinary Tract Infection			
subjects affected / exposed	6 / 56 (10.71%)	2 / 20 (10.00%)	
occurrences (all)	8	2	
Vaginal Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Viral Infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	26 / 56 (46.43%)	7 / 20 (35.00%)	
occurrences (all)	31	7	
Dehydration			
subjects affected / exposed	4 / 56 (7.14%)	1 / 20 (5.00%)	
occurrences (all)	4	1	
Fluid Overload			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hypercalcaemia			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Hypercholesterolaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	1 / 56 (1.79%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Hyperkalaemia			
subjects affected / exposed	1 / 56 (1.79%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Hypermagnesaemia			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypernatraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypertriglyceridaemia			
subjects affected / exposed	2 / 56 (3.57%)	0 / 20 (0.00%)	
occurrences (all)	3	0	
Hyperuricaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia			
subjects affected / exposed	3 / 56 (5.36%)	1 / 20 (5.00%)	
occurrences (all)	3	1	
Hypocalcaemia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hypoglycaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	12 / 56 (21.43%)	3 / 20 (15.00%)	
occurrences (all)	17	5	
Hypomagnesaemia			
subjects affected / exposed	10 / 56 (17.86%)	1 / 20 (5.00%)	
occurrences (all)	20	2	
Hyponatraemia			
subjects affected / exposed	6 / 56 (10.71%)	2 / 20 (10.00%)	
occurrences (all)	11	3	
Hypophagia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hypophosphataemia			
subjects affected / exposed	4 / 56 (7.14%)	2 / 20 (10.00%)	
occurrences (all)	7	2	
Iron Deficiency			

subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Malnutrition			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Polydipsia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vitamin D Deficiency			
subjects affected / exposed	1 / 56 (1.79%)	0 / 20 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 December 2016	Included melanoma cancer as an additional indication in the trial. Inclusion/exclusion criteria were updated. Genetic and proteomic analyses were removed. Updated and clarified the sampling, timing, specification, handling and methods of the exploratory analyses. Storage of the biological samples in the trial was clarified.
25 September 2017	Introduced the updated mitigation plan for handling of constipation and introduced safety blood samples collected locally 24 hours prior to each study drug administration. Clarified the visit window of Cycle 2 Visit 1 in order to ensure that the DLT evaluation period during Cycle 1 completed as planned before initiation of Cycle 2. Updated time windows for some of the assessments of vital signs in order to allow for practical and safe assessments.
12 April 2018	An arm with platinum-resistant ovarian cancer participants was added to the Expansion part of the trial; this also increased the planned number of participants. An interim analysis for futility for all cohorts was introduced, which provided a mechanism to reduce the number of participants exposed to a potentially inefficient experimental therapy. Participants who benefit from the treatment were offered continued treatment within the scope of the protocol until their disease progressed or until they experienced unacceptable toxicity. A subject diary was introduced in order to capture information on prophylactic use of stool softeners to prevent constipation. The diary also captured changes in stool frequency and consistency.
11 October 2018	Additional participants to be enrolled in Cohort 2 were added due to observation of an efficacy signal in participants without drug-sensitizing mutations treated for NSCLC. Clarified that in Cohort 2, only participants with wild-type EGFR should be enrolled, ie, not only participants without the classical sensitizing EGFR mutations but also without the resistance mutations such as T790M, targeted by third generation tyrosine kinase inhibitors (TKIs). Newly identified risks, including peripheral neuropathy and neutropenia, were described for enapotamab vedotin in Version 4.0 of the Investigator’s Brochure (IB). Based on this IB update, new participants were added describing the relevant safety findings. Changed the INN name for HuMax-AXL-ADC to enapotamab vedotin. Expansion part 'cohort(s)' used throughout the protocol instead of arm(s).
07 December 2018	Modified some of the inclusion criteria for the expansion cohorts to further define the exact target subject population and to guard participant safety during the study. Due to emerging safety data, a new subsection on dose modifications for immune-related AEs (irAEs) was introduced for optimal management of these events. The possibility to conduct further safety review after 36 and 100 participants in the Expansion part was added.

18 June 2019	Excluded participants with ongoing pneumonitis at Screening or with a history of noninfectious pneumonitis that required steroids. Allowed for inclusion of participants who had pneumonitis (asymptomatic, did not require steroid treatment, and had no radiological evidence) in the past if more than 6 months prior to enrollment. Increased the treatment interruption window period to maximize the clinical benefit for participants. Clarified that every effort should be made to document disease progression by radiological imaging and RECIST even though participant was discontinued from trial treatment (eg, due to an AE). Based on negative emerging data that showed absence of AXL+ circulating tumor cells (CTCs) in post-PD(L)1 NSCLC participants, CTC assessments were no longer considered useful evaluating this trial drug. Clarified text around confirmation of response according to RECIST and guidance added around scans in case of discontinuation due to an AE. Clarified timing of scans and unscheduled scans. Clarified that both investigator disease assessments as well as Independent Review Committee assessment would be used for analysis. Added clarification on expectations where bronchoscopy-guided biopsies were allowed. Noted that the information on investigator assessment of the clinical significance of laboratory values was not included in the Study Data Tabulation Model dataset and therefore could not be extracted for inclusion in listings. The treatment algorithm was changed from a limited number of cycles to treatment until progression of the underlying disease per RECIST was detected.
21 October 2019	Implemented more stringent dose modification guidance for TEAEs of peripheral neuropathy. Modified PK sampling. In an attempt to improve the observed tolerability profile and expand the possible therapeutic window for enapotamab vedotin, a limited number of participants could be enrolled in Cohort 2 on a starting dose of 1.8 mg/kg. In order to obtain 25 fresh biopsies from Cohort 6, up to 15 additional participants could be recruited. Implemented to further explore the potential of the maximum tolerated dose (MTD) of the 3Q4W schedule. Clarified that adjuvant or maintenance treatment would be counted as 1 regimen, together with the relevant surgery or primary treatment. Revised inclusion criteria as the reference to adjuvant and maintenance treatment was no longer relevant for the inclusion criterion. Relaxed the restriction criteria, as the restriction of up to 3 lines of prior treatment proved to be challenging for enrollment as many participants failed more than 3 lines. Clarified how long dosing could be delayed for and how the resumption of dosing should be handled for the 3Q4W dosing schedule. Spain was included as a country in the trial.
09 December 2019	Added Cohort 8 to further explore, in the same participant population as Cohort 2, the 1.0 mg/kg 3Q4W schedule adding up to 37 participants to be treated. Added a rationale for the subgroup of the participants in Cohort 2 at a dose of 1.8 mg/kg, which was not included in Amendment dated 21 October 2019. Excluded participants who experienced hyper-progressive disease during prior checkpoint inhibitor therapy. Reduced number of visits as visits were a burden for participants. Clarified PK assessments for Expansion. Added peripheral neuropathy reporting requirements to enhance data collection and facilitate the understanding and characterization of the event. Clarified data summarized for participants with NSCLC without EGFR/ALK mutations. Removed interim analysis for futility for Cohorts 6 and 8.
30 June 2021	To allow analysis and reporting of the trial, while permitting the 3 remaining participants to stay on treatment and be followed per protocol. At the time of this Amendment, the Dose Escalation part and the enrollment of the Expansion part of trial had been completed; 3 participants remained on treatment. The 3 participants had been on treatment for at least 7 months, which was considered sufficient to evaluate efficacy and safety. With this amendment, the 3 participants still on treatment continued treatment and were followed with reduced procedures and visits. Sections Statistical Analysis, Interim Analyses, and Clinical Trial Reporting were revised to reflect the analysis of efficacy and safety per data cut-off date and clinical trial reporting plans. The plan to present corrected QT interval analyses in a separate report was removed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No participants with castration-resistant prostate cancer were enrolled, hence no prostate-specific antigen (PSA) data were available and pre-specified outcome measure related to PSA data are not reported.

Notes: