



Clinical trial results: Open-Label Phase 2 Study of Ladiratuzumab Vedotin (LV) for Unresectable Locally Advanced or Metastatic Solid Tumors Summary

EudraCT number	2019-001946-17
Trial protocol	GB IT
Global end of trial date	28 November 2023

Results information

Result version number	v1 (current)
This version publication date	07 December 2024
First version publication date	07 December 2024

Trial information

Trial identification

Sponsor protocol code	C5741002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04032704
WHO universal trial number (UTN)	-
Other trial identifiers	Seagen: SGNLVA-005

Notes:

Sponsors

Sponsor organisation name	Seagen Inc.
Sponsor organisation address	21823 30th Drive S.E., Bothell, United States, 98021
Public contact	Chief Medical Officer, Seagen Inc., 1 8554732436, medinfo@seagen.com
Scientific contact	Chief Medical Officer, Seagen Inc., 1 8554732436, medinfo@seagen.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	17 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate antitumor activity of LV as monotherapy (Part A, Part B, and Part C Arm 1 [Cohort 8 only]) and in combination with pembrolizumab (Part C Arm 2 and Arm 3, Cohort 8 only)

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 October 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	38 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 28
Country: Number of subjects enrolled	Italy: 34
Country: Number of subjects enrolled	Korea, Republic of: 28
Country: Number of subjects enrolled	Taiwan: 9
Country: Number of subjects enrolled	United Kingdom: 22
Country: Number of subjects enrolled	United States: 84
Worldwide total number of subjects	205
EEA total number of subjects	34

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)	108
From 65 to 84 years	93
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

This study had Parts A, B and C. Study was terminated and Part C was not opened. A total of 205 participants were enrolled in Part A (49 participants) and Part B (156 participants) of this study. In Part A all enrolled participants received study intervention while in Part B, 2 participants did not receive study intervention.

Pre-assignment

Screening details:

Cohort (C): C1:small cell lung cancer (SCLC) [A, B]; C2:non-SCLC-squamous (sq)[NSCLC-sq] {A, B}; C3:NSCLC-nonsq (A, B); C4:head & neck sq cell carcinoma (SCC)[HNSCC] {A, B}; C5: esophageal SSC (esophageal-sq)[A, B]; C6:gastric & gastroesophageal junction(GEJ) adenocarcinoma (A, B); C7:castration-resistant prostate cancer(CRPC) (B);C8:melanoma (B).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: Cohort 1, LV 2.5 mg/kg

Arm description:

Participants with SCLC were administered ladiratuzumab vedotin (LV) 2.5 milligram per kilogram (mg/kg) as intravenous (IV) infusion on Day 1 of each 21-day cycle (q3wk).

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 2.5 mg/kg as an IV infusion on Day 1 q3wk.

Arm title	Part A: Cohort 2, LV 2.5 mg/kg
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Arm description:

Participants with NSCLC-squamous were administered LV 2.5 mg/kg as IV infusion q3wk.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 2.5 mg/kg as an IV infusion on Day 1 q3wk.

Arm title	Part A: Cohort 3, LV 2.5 mg/kg
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Arm description:

Participants with NSCLC-nonsquamous were administered LV 2.5 mg/kg as IV infusion q3wk.

Arm type	Experimental
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Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received LV 2.5 mg/kg as an IV infusion on Day 1 q3wk.	
Arm title	Part A: Cohort 4, LV 2.5 mg/kg
Arm description:	
Participants with HNSCC were administered LV 2.5 mg/kg as IV infusion q3wk.	
Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received LV 2.5 mg/kg as an IV infusion on Day 1 q3wk.	
Arm title	Part A: Cohort 5, LV 2.5 mg/kg
Arm description:	
Participants with esophageal-squamous were administered LV 2.5 mg/kg as IV infusion q3wk.	
Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received LV 2.5 mg/kg as an IV infusion on Day 1 q3wk.	
Arm title	Part A: Cohort 6, LV 2.5 mg/kg
Arm description:	
Participants with GEJ were administered LV 2.5 mg/kg as IV infusion q3wk.	
Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received LV 2.5 mg/kg as an IV infusion on Day 1 q3wk.	
Arm title	Part B: Cohort 1, LV 1.25 mg/kg
Arm description:	
Participants with SCLC were administered LV 1.25 mg/kg on Days 1, 8 and 15 of each 21-day cycle (q1wk) as a 30-minute IV infusion.	
Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 2, LV 1.25 mg/kg
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Arm description:

Participants with NSCLC-squamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 3, LV 1.25 mg/kg
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Arm description:

Participants with NSCLC-nonsquamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 4, LV 1.25 mg/kg
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Arm description:

Participants with HNSCC were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 5, LV 1.25 mg/kg
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Arm description:

Participants with esophageal-squamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 6, LV 1.25 mg/kg
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Arm description:

Participants with GEJ were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 7, LV 1.25 mg/kg
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Arm description:

Participants with CRPC were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 8, LV 1.25 mg/kg
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Arm description:

Participants with melanoma were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.25 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 1, LV 1.0 mg/kg
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Arm description:

Participants with SCLC were administered LV 1.0 mg/kg q1wk on Days 1, 8 and 15 as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.0 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 3, LV 1.0 mg/kg
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Arm description:

Participants with NSCLC-nonsquamous were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.0 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 4, LV 1.0 mg/kg
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Arm description:

Participants with HNSCC were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.0 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Arm title	Part B: Cohort 6, LV 1.0 mg/kg
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Arm description:

Participants with GEJ were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.

Arm type	Experimental
Investigational medicinal product name	Ladiratuzumab vedotin (LV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received LV 1.0 mg/kg as an IV infusion on Day 1, 8 and 15 q3wk.

Number of subjects in period 1	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg
Started	10	2	13
Completed	0	0	0
Not completed	10	2	13
Adverse event, serious fatal	9	2	10
Study termination by Sponsor	-	-	-
Consent withdrawn by subject	-	-	3
Unspecified	-	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Part A: Cohort 4, LV 2.5 mg/kg	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg
Started	7	5	12
Completed	0	0	0
Not completed	7	5	12
Adverse event, serious fatal	7	4	5
Study termination by Sponsor	-	-	-
Consent withdrawn by subject	-	1	7
Unspecified	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg
Started	16	16	19
Completed	0	0	0
Not completed	16	16	19
Adverse event, serious fatal	13	13	14
Study termination by Sponsor	-	-	1
Consent withdrawn by subject	3	2	2
Unspecified	-	1	2
Lost to follow-up	-	-	-

Number of subjects in period 1	Part B: Cohort 4, LV 1.25 mg/kg	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg
Started	14	17	21
Completed	0	0	0
Not completed	14	17	21
Adverse event, serious fatal	12	12	13
Study termination by Sponsor	-	-	-
Consent withdrawn by subject	1	4	6
Unspecified	1	1	1
Lost to follow-up	-	-	1

Number of subjects in period 1	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg	Part B: Cohort 1, LV 1.0 mg/kg
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Started	14	31	2
Completed	0	0	0
Not completed	14	31	2
Adverse event, serious fatal	7	17	2
Study termination by Sponsor	-	-	-
Consent withdrawn by subject	2	1	-
Unspecified	5	13	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Started	2	2	2
Completed	0	0	0
Not completed	2	2	2
Adverse event, serious fatal	1	2	2
Study termination by Sponsor	-	-	-
Consent withdrawn by subject	1	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Part A: Cohort 1, LV 2.5 mg/kg
Reporting group description: Participants with SCLC were administered ladiratuzumab vedotin (LV) 2.5 milligram per kilogram (mg/kg) as intravenous (IV) infusion on Day 1 of each 21-day cycle (q3wk).	
Reporting group title	Part A: Cohort 2, LV 2.5 mg/kg
Reporting group description: Participants with NSCLC-squamous were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 3, LV 2.5 mg/kg
Reporting group description: Participants with NSCLC-nonsquamous were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 4, LV 2.5 mg/kg
Reporting group description: Participants with HNSCC were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 5, LV 2.5 mg/kg
Reporting group description: Participants with esophageal-squamous were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 6, LV 2.5 mg/kg
Reporting group description: Participants with GEJ were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part B: Cohort 1, LV 1.25 mg/kg
Reporting group description: Participants with SCLC were administered LV 1.25 mg/kg on Days 1, 8 and 15 of each 21-day cycle (q1wk) as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 2, LV 1.25 mg/kg
Reporting group description: Participants with NSCLC-squamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 3, LV 1.25 mg/kg
Reporting group description: Participants with NSCLC-nonsquamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 4, LV 1.25 mg/kg
Reporting group description: Participants with HNSCC were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 5, LV 1.25 mg/kg
Reporting group description: Participants with esophageal-squamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 6, LV 1.25 mg/kg
Reporting group description: Participants with GEJ were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 7, LV 1.25 mg/kg
Reporting group description: Participants with CRPC were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 8, LV 1.25 mg/kg
Reporting group description: Participants with melanoma were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	

Reporting group title	Part B: Cohort 1, LV 1.0 mg/kg
Reporting group description: Participants with SCLC were administered LV 1.0 mg/kg q1wk on Days 1, 8 and 15 as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 3, LV 1.0 mg/kg
Reporting group description: Participants with NSCLC-nonsquamous were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 4, LV 1.0 mg/kg
Reporting group description: Participants with HNSCC were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 6, LV 1.0 mg/kg
Reporting group description: Participants with GEJ were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	

Reporting group values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg
Number of subjects	10	2	13
Age categorical Units: Participants			
Adults (18-64 years)	5	0	6
From 65-84 years	5	2	6
85 years and over	0	0	1
Age Continuous Units: Years			
arithmetic mean	63.7	80.5	67.2
standard deviation	± 9.5	± 4.9	± 13.7
Sex: Female, Male Units: Participants			
Female	2	1	8
Male	8	1	5
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	1
White	5	2	10
More than one race	0	0	0
Unknown or Not Reported	1	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	10	2	13
Unknown or Not Reported	0	0	0

Reporting group values	Part A: Cohort 4, LV 2.5 mg/kg	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg
Number of subjects	7	5	12

Age categorical Units: Participants			
Adults (18-64 years)	4	2	7
From 65-84 years	3	2	5
85 years and over	0	1	0
Age Continuous Units: Years			
arithmetic mean	63.1	70.8	64.7
standard deviation	± 12.3	± 11.2	± 10.3
Sex: Female, Male Units: Participants			
Female	2	1	0
Male	5	4	12
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	4	8
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	6	1	4
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	5	12
Unknown or Not Reported	0	0	0

Reporting group values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg
Number of subjects	16	16	19
Age categorical Units: Participants			
Adults (18-64 years)	9	6	10
From 65-84 years	6	10	9
85 years and over	1	0	0
Age Continuous Units: Years			
arithmetic mean	65.0	67.3	63.9
standard deviation	± 10.7	± 8.8	± 9.3
Sex: Female, Male Units: Participants			
Female	7	4	5
Male	9	12	14
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	1	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	14	13	14

More than one race	0	0	0
Unknown or Not Reported	0	2	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	15	13	18
Unknown or Not Reported	1	2	1

Reporting group values	Part B: Cohort 4, LV 1.25 mg/kg	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg
Number of subjects	14	17	21
Age categorical			
Units: Participants			
Adults (18-64 years)	8	13	14
From 65-84 years	6	4	7
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	63.8	60.5	60.9
standard deviation	± 9.9	± 8.3	± 8.9
Sex: Female, Male			
Units: Participants			
Female	3	2	3
Male	11	15	18
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	9	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	11	5	12
More than one race	0	0	0
Unknown or Not Reported	1	3	5
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	14	14	16
Unknown or Not Reported	0	3	4

Reporting group values	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg	Part B: Cohort 1, LV 1.0 mg/kg
Number of subjects	14	31	2
Age categorical			
Units: Participants			
Adults (18-64 years)	4	15	2
From 65-84 years	9	16	0
85 years and over	1	0	0
Age Continuous			
Units: Years			
arithmetic mean	71.6	62.9	61.0
standard deviation	± 8.3	± 12.2	± 1.4

Sex: Female, Male			
Units: Participants			
Female	0	8	0
Male	14	23	2
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	3	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	10	26	2
More than one race	0	0	0
Unknown or Not Reported	3	2	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	28	2
Unknown or Not Reported	2	3	0

Reporting group values	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Number of subjects	2	2	2
Age categorical			
Units: Participants			
Adults (18-64 years)	1	2	0
From 65-84 years	1	0	2
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	66.0	56.0	77.5
standard deviation	± 2.8	± 2.8	± 6.4
Sex: Female, Male			
Units: Participants			
Female	1	0	0
Male	1	2	2
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	2	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	1	2	2
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	205		
Age categorical			
Units: Participants			
Adults (18-64 years)	108		
From 65-84 years	93		
85 years and over	4		
Age Continuous			
Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: Participants			
Female	47		
Male	158		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	41		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	5		
White	141		
More than one race	0		
Unknown or Not Reported	18		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	3		
Not Hispanic or Latino	186		
Unknown or Not Reported	16		

End points

End points reporting groups

Reporting group title	Part A: Cohort 1, LV 2.5 mg/kg
Reporting group description: Participants with SCLC were administered ladiratuzumab vedotin (LV) 2.5 milligram per kilogram (mg/kg) as intravenous (IV) infusion on Day 1 of each 21-day cycle (q3wk).	
Reporting group title	Part A: Cohort 2, LV 2.5 mg/kg
Reporting group description: Participants with NSCLC-squamous were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 3, LV 2.5 mg/kg
Reporting group description: Participants with NSCLC-nonsquamous were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 4, LV 2.5 mg/kg
Reporting group description: Participants with HNSCC were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 5, LV 2.5 mg/kg
Reporting group description: Participants with esophageal-squamous were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part A: Cohort 6, LV 2.5 mg/kg
Reporting group description: Participants with GEJ were administered LV 2.5 mg/kg as IV infusion q3wk.	
Reporting group title	Part B: Cohort 1, LV 1.25 mg/kg
Reporting group description: Participants with SCLC were administered LV 1.25 mg/kg on Days 1, 8 and 15 of each 21-day cycle (q1wk) as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 2, LV 1.25 mg/kg
Reporting group description: Participants with NSCLC-squamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 3, LV 1.25 mg/kg
Reporting group description: Participants with NSCLC-nonsquamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 4, LV 1.25 mg/kg
Reporting group description: Participants with HNSCC were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 5, LV 1.25 mg/kg
Reporting group description: Participants with esophageal-squamous were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 6, LV 1.25 mg/kg
Reporting group description: Participants with GEJ were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 7, LV 1.25 mg/kg
Reporting group description: Participants with CRPC were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 8, LV 1.25 mg/kg
Reporting group description: Participants with melanoma were administered LV 1.25 mg/kg on Days 1, 8 and 15 q1wk as a 30-	

minute IV infusion.

Reporting group title	Part B: Cohort 1, LV 1.0 mg/kg
Reporting group description: Participants with SCLC were administered LV 1.0 mg/kg q1wk on Days 1, 8 and 15 as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 3, LV 1.0 mg/kg
Reporting group description: Participants with NSCLC-nonsquamous were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 4, LV 1.0 mg/kg
Reporting group description: Participants with HNSCC were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	
Reporting group title	Part B: Cohort 6, LV 1.0 mg/kg
Reporting group description: Participants with GEJ were administered LV 1.0 mg/kg on Days 1, 8 and 15 q1wk as a 30-minute IV infusion.	

Primary: Part A: Confirmed Objective Response Rate (ORR) as Determined by Investigator According to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)

End point title	Part A: Confirmed Objective Response Rate (ORR) as Determined by Investigator According to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) ^{[1][2]}
End point description: Confirmed ORR was defined as the percentage of participants with a confirmed complete response (CR) or partial response (PR) per RECIST v.1.1. CR was defined as disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to less than (<) 10 millimeter (mm). PR was defined as more than or equal to (>=) 30 percent (%) decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Participants who did not have at least 2 post-baseline response assessment (initial response and confirmation scan) were counted as non-responders. The full analysis set (FAS) included all participants who received any amount of study drug.	
End point type	Primary
End point timeframe: From the first dose of study treatment until the first documented CR or PR or new anticancer therapies or death, whichever occurred first (maximum up to 8.3 months)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

[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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	13	7
Units: Percentage of participants				
number (confidence interval 95%)	10 (0.3 to 44.5)	0 (0.0 to 84.2)	8 (0.2 to 36.0)	14 (0.4 to 57.9)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Percentage of participants				
number (confidence interval 95%)	20 (0.5 to 71.6)	8 (0.2 to 38.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Confirmed ORR as Determined by Investigator According to RECIST v1.1

End point title	Part B: Confirmed ORR as Determined by Investigator According to RECIST v1.1 ^[3] ^[4]
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End point description:

Confirmed ORR was defined as the percentage of participants with a confirmed CR or PR per RECIST v.1.1. CR was defined as disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to < 10 mm. PR was defined as $\geq 30\%$ decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Participants who did not have at least 2 post-baseline response assessment (initial response and confirmation scan) were counted as non-responders. The FAS included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From the first dose of study treatment until the first documented CR or PR or new anticancer therapies or death, whichever occurred first (maximum up to 34.7 months for 1.25 mg/kg and 5.7 months for 1 mg/kg dose level)

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: This endpoint was planned to be analysed only for the specified reporting arms.

[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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	19	14
Units: Percentage of participants				
number (confidence interval 95%)	6 (0.2 to 30.2)	13 (1.6 to 38.3)	11 (1.3 to 33.1)	0 (0.0 to 23.2)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	13	30
Units: Percentage of participants				
number (confidence interval 95%)	18 (3.8 to 43.4)	14 (3.0 to 36.3)	0 (0.0 to 24.7)	20 (7.7 to 38.6)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	2
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 84.2)	0 (0.0 to 84.2)	0 (0.0 to 84.2)	50 (1.3 to 98.7)

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Confirmed Prostate-Specific Antigen (PSA) Response Rate as Determined by Investigator According to Prostate Cancer Clinical Trials Working Group 3 (PCWG3) Criteria, for Prostate Cancer

End point title	Part B: Confirmed Prostate-Specific Antigen (PSA) Response Rate as Determined by Investigator According to Prostate Cancer Clinical Trials Working Group 3 (PCWG3) Criteria, for Prostate Cancer ^{[5][6]}
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End point description:

Confirmed PSA response rate was defined as percentage of participants with reduction from baseline PSA level of at least 50%, measured twice ≥ 3 weeks apart. PSA progression was defined as per PCWG3 criteria- a) if a participant presented first a decline from baseline, progression was defined as the first PSA increase that was $\geq 25\%$ and ≥ 2 nanograms per milliliter (ng/mL) above the nadir, and which was confirmed by a consecutive second value ≥ 3 weeks later that fulfilled the same criteria (that is, a confirmed rising trend); b) if a participant did not present a decline from baseline, progression was defined as the first PSA increase that was $\geq 25\%$ and ≥ 2 ng/mL increased from baseline beyond 12 weeks. The FAS included all participants who received any amount of study drug. As prespecified in protocol, this endpoint was planned to be analysed only in Part B: Cohort 7, LV 1.25 mg/kg arm. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint.

End point type	Primary
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End point timeframe:

From the first dose of study treatment up to the date of last response assessment (maximum up to 13.5 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

[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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 7, LV 1.25 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Percentage of participants				
number (confidence interval 95%)	23 (5.0 to 53.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Participants With Treatment Emergent Adverse Events (TEAEs), Treatment Emergent Serious Adverse Events (TESAEs), Treatment Related TEAEs and >= Grade 3 TEAE

End point title	Part A: Number of Participants With Treatment Emergent Adverse Events (TEAEs), Treatment Emergent Serious Adverse Events (TESAEs), Treatment Related TEAEs and >= Grade 3 TEAE ^[7]
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End point description:

Adverse event (AE) was any untoward medical occurrence in a participant/ clinical investigational participant administered a medicinal product and which does not necessarily have a causal relationship with this treatment. AEs included both SAEs and all non-SAEs. TEAEs were defined as newly occurring (not present at baseline)/worsening after first dose of study treatment. TESAEs were any untoward medical occurrence at any dose that: suspected to cause death; life-threatening; required hospitalization; persistent/significant disability/incapacity & may cause congenital anomaly/birth defect. Treatment related TEAEs were related to study treatment and relatedness was judged by investigator. TEAEs were graded according to National Cancer Institute, Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version (v) 4.03 (grade 1= mild, grade 2= moderate, grade 3= severe and grade 4= life-threatening). Safety analysis set included all participants who received any amount of study drug.

End point type	Secondary
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End point timeframe:

From start of study treatment up to 30 days after last dose of study treatment (maximum up to 37.5 months)

Notes:

[7] - 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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	13	7
Units: Participants				
TEAEs	10	2	13	7
TESAEs	5	1	7	2
Treatment Related TEAEs	9	2	11	7
TEAEs (>= Grade 3)	7	1	9	4

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Participants				
TEAEs	5	12		
TESAEs	3	3		
Treatment Related TEAEs	5	11		
TEAEs (>= Grade 3)	4	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With TEAEs, TESAEs, Treatment Related TEAEs and >= Grade 3 TEAE

End point title	Part B: Number of Participants With TEAEs, TESAEs, Treatment Related TEAEs and >= Grade 3 TEAE ^[8]
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End point description:

AE was any untoward medical occurrence in participant, or clinical investigational participant administered medicinal product, and which does not necessarily have causal relationship with this treatment. AEs included both SAEs and all non-SAEs. TEAEs were defined as newly occurring (not present at baseline) or worsening after first dose of study treatment. TESAEs were any untoward medical occurrence at any dose that: suspected to cause death; life-threatening; required hospitalisation; persistent or significant disability or incapacity and may cause congenital anomaly or birth defect. Treatment related TEAEs were related to study treatment and relatedness was judged by investigator. TEAEs were graded according to NCI-CTCAE v4.03 (grade 1= mild, grade 2= moderate, grade 3= severe and grade 4= life-threatening). Safety analysis set included all participants who received any amount of study drug.

End point type	Secondary
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End point timeframe:

From start of study treatment up to 30 days after last dose of study treatment (maximum up to 37.5 months)

Notes:

[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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	19	14
Units: Participants				
TEAEs	15	16	19	14
TESAEs	6	5	9	8
Treatment Related TEAEs	13	16	18	12
TEAEs (>= Grade 3)	12	11	14	11

End point values	Part B: Cohort	Part B: Cohort	Part B: Cohort	Part B: Cohort
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	5, LV 1.25 mg/kg	6, LV 1.25 mg/kg	7, LV 1.25 mg/kg	8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	13	30
Units: Participants				
TEAEs	17	21	13	30
TESAEs	9	12	4	11
Treatment Related TEAEs	17	19	12	28
TEAEs (>= Grade 3)	13	17	8	17

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	2
Units: Participants				
TEAEs	2	2	2	2
TESAEs	1	2	1	0
Treatment Related TEAEs	2	2	2	2
TEAEs (>= Grade 3)	1	2	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Confirmed Investigator Determined Disease Control Rate (DCR) According to RECIST v1.1

End point title	Part A: Confirmed Investigator Determined Disease Control Rate (DCR) According to RECIST v1.1 ^[9]
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End point description:

DCR: percentage of participants who achieved confirmed and unconfirmed CR/PR per RECIST v1.1 or met stable disease (SD) criteria at least once after start of study treatment at minimum interval of 5 weeks. CR: disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to <10 mm. PR: >= 30% decrease in sum of diameters of target lesions, taking as reference baseline sum diameters. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD), taking as reference smallest sum diameters while on study. PD: at least 20% increase in sum of diameters of target lesions, taking as reference smallest sum on study (this included baseline sum if that is smallest). In addition to relative increase of 20%, sum must also demonstrate an absolute increase of at least 0.5cm. Appearance of one or more new lesions was also considered progression. FAS: all participants who received any amount of study drug.

End point type	Secondary
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End point timeframe:

From the first dose of study treatment until the first documented CR, PR or SD or new anticancer therapies or death, whichever occurred first (maximum up to 4.1 months)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	13	7
Units: Percentage of participants				
number (confidence interval 95%)	40 (12.2 to 73.8)	50 (1.3 to 98.7)	46 (19.2 to 74.9)	57 (18.4 to 90.1)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Percentage of participants				
number (confidence interval 95%)	60 (14.7 to 94.7)	33 (9.9 to 65.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Confirmed Investigator Determined DCR According to RECIST v1.1

End point title	Part B: Confirmed Investigator Determined DCR According to RECIST v1.1 ^[10]
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End point description:

DCR: percentage of participants who achieved confirmed and unconfirmed CR/PR per RECIST v1.1 or met SD criteria at least once after start of study treatment at minimum interval of 5 weeks. CR: disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to <10mm. PR: \geq 30% decrease in sum of diameters of target lesions, taking as reference baseline sum diameters. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference smallest sum diameters. PD: at least 20% increase in sum of diameters of target lesions, taking as reference smallest sum on study (this included baseline sum if that is smallest). In addition to relative increase of 20%, sum must also demonstrate absolute increase of at least 0.5 centimeter (cm). Appearance of one or more new lesions was also considered progression. FAS: all participants who received any amount of study drug. 'N'= participants evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

From the first dose of study treatment until the first documented CR, PR or SD or new anticancer therapies or death, whichever occurred first (maximum up to 5.5 months for 1.25 mg/kg and 1.5 months for 1 mg/kg dose level)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	19	14
Units: Percentage of participants				
number (confidence interval 95%)	19 (4.0 to 45.6)	50 (24.7 to 75.3)	58 (33.5 to 79.7)	64 (35.1 to 87.2)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	13	30
Units: Percentage of participants				
number (confidence interval 95%)	59 (32.9 to 81.6)	52 (29.8 to 74.3)	62 (31.6 to 86.1)	77 (57.7 to 90.1)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	2
Units: Percentage of participants				
number (confidence interval 95%)	50 (1.3 to 98.7)	50 (1.3 to 98.7)	0 (0.0 to 84.2)	100 (15.8 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Confirmed Investigator Determined Duration of Response (DOR) According to RECIST v1.1

End point title	Part A: Confirmed Investigator Determined Duration of Response (DOR) According to RECIST v1.1 ^[11]
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End point description:

DOR: time from 1st documentation of OR to 1st documentation of PD/death due to any cause, whichever occurred first. CR: disappearance of target lesions (TL). Pathological lymph nodes must have reduction in short axis to <10mm. PR: $\geq 30\%$ decrease in sum of diameters of TL. Participants don't have PD, are on study at time of analysis/removed from study prior to documentation of PD = censored at last disease assessment (DA) documenting absence of PD. Participants who started new anticancer treatment prior to documentation of PD = censored at last DA prior to start of new treatment. PD: at least 20% increase in sum of diameters of TL. Sum must demonstrate increase of 0.5 cm. Appearance of 1/more new lesions = progression. Kaplan-Meier method was used. FAS analysed. 'N'=participants evaluable for endpoint. 99999 = 1 participant evaluable, lower & upper limit (UL) of 95% CI could not be estimated. 88888 = no participant had event of interest; results could not be estimated.

End point type	Secondary
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End point timeframe:

From the first documentation of CR or PR to PD or death or censoring whichever occurred first (maximum up to 5.7 months)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0 ^[12]	1	1
Units: Months				
median (confidence interval 95%)	5.7 (-99999 to 99999)	(to)	5.5 (-99999 to 99999)	3.7 (-99999 to 99999)

Notes:

[12] - No participant had CR or PR in this arm.

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: Months				
median (confidence interval 95%)	2.7 (-99999 to 99999)	88888 (-88888 to 88888)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Confirmed Investigator Determined DOR According to RECIST v1.1

End point title	Part B: Confirmed Investigator Determined DOR According to RECIST v1.1 ^[13]
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End point description:

DOR: time from 1st documentation (doc) of OR to 1st doc of PD/death due to any cause, whichever occurred 1st. CR: disappearance of TL. Pathological lymph nodes must have reduction in short axis to <10mm. PR: ≥30% decrease in sum of diameters of TL. Participants don't have PD, are on study at time of analysis/removed from study prior to doc of PD was censored at last disease assessment (DA) documenting absence of PD. Participants who started new anticancer treatment prior to doc of PD=censored at last DA prior to start of new treatment. PD: at least 20% increase (inc) in sum of diameters of TL. Sum must demonstrate inc of 0.5cm. Appearance of 1/more new lesions=progression. Kaplan-Meier method was used. FAS analysed. 'N'=participants evaluable for endpoint. 99999=1 participant evaluable, lower & UL of 95% CI could not be estimated. 88888= no participant had event of interest; results could not be estimated. 77777= insufficient number of participants with events to calculate UL of 95%CI.

End point type	Secondary
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End point timeframe:

From the first documentation of CR or PR to PD or death or censoring whichever occurred first (maximum up to 32.0 months for 1.25 mg/kg and 4.2 months for 1 mg/kg dose level)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	2	0 ^[14]
Units: Months				
median (confidence interval 95%)	88888 (-88888 to 88888)	7.5 (5.78 to 77777)	77777 (16.59 to 77777)	(to)

Notes:

[14] - No participant had CR or PR in this arm.

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	0 ^[15]	6
Units: Months				
median (confidence interval 95%)	77777 (3.06 to 77777)	3.9 (2.60 to 77777)	(to)	8.3 (5.62 to 77777)

Notes:

[15] - No participant had CR or PR in this arm.

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[16]	0 ^[17]	0 ^[18]	1
Units: Months				
median (confidence interval 95%)	(to)	(to)	(to)	4.2 (-99999 to 99999)

Notes:

[16] - No participant had CR or PR in this arm.

[17] - No participant had CR or PR in this arm.

[18] - No participant had CR or PR in this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Confirmed Investigator Determined PSA-DOR, for Prostate Cancer

End point title	Part B: Confirmed Investigator Determined PSA-DOR, for Prostate Cancer ^[19]
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End point description:

PSA-DOR=time from 1st documentation of PSA response(confirmed 3 weeks apart)to 1st documentation of PSA progression/death due to any cause,whichever occurred first.Confirmed PSA response rate=percentage of participants with reduction from baseline PSA of 50%,measured twice >=3 weeks apart.Participants who don't have PD,are still on study at time of analysis/removed from study prior to documentation of PD was censored at date of last disease assessment documenting absence of PD.Participants who started new anticancer treatment prior to documentation of PD were censored at date of last disease assessment prior to start of new treatment.Confidence interval (CI) calculated by complementary log-log transformation method.FAS=participants who received any amount of drug.As

prespecified in protocol, endpoint was planned to be analysed only in Part B: Cohort 7, LV 1.25mg/kg arm. 'N' = participants evaluable for endpoint. 77777 = insufficient participants with events to calculate upper limit of 95% CI.

End point type	Secondary
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End point timeframe:

From the first documentation of CR or PR to PD or death or censoring whichever occurred first (maximum up to 3 months)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 7, LV 1.25 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Months				
median (confidence interval 95%)	3.0 (1.9 to 77777)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Confirmed Investigator Determined Progression Free Survival (PFS) According to RECIST v1.1

End point title	Part A: Confirmed Investigator Determined Progression Free Survival (PFS) According to RECIST v1.1 ^[20]
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End point description:

PFS: time from start of study treatment to 1st documentation of PD by RECIST v1.1. Participants who do not have PD, are still on study at time of analysis/removed from study prior to documentation of PD were censored at date of last disease assessment documenting absence of PD. Participants who started new anticancer treatment prior to documentation of PD were censored at date of last disease assessment prior to start of new treatment. PD: at least 20% increase in sum of diameters of target lesions, taking as reference smallest sum on study (this included baseline sum if that is smallest on study). Sum must also demonstrate absolute increase of at least 0.5cm. Appearance of 1 or more new lesions was considered progression. Median was estimated using Kaplan-Meier method; CI was calculated using complementary log-log transformation method. FAS = all participants who received any amount of study drug. 77777 = insufficient number of participants with events to calculate upper limit of 95% CI.

End point type	Secondary
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End point timeframe:

From first dose of study treatment to the date of PD or clinical PD or censoring whichever occurred first (maximum up to 8.3 months)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	13	7
Units: Months				
median (confidence interval 95%)	1.4 (0.53 to 2.69)	1.5 (1.25 to 77777)	2.5 (0.46 to 4.17)	2.3 (0.33 to 4.86)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Months				
median (confidence interval 95%)	2.9 (0.59 to 77777)	1.4 (1.31 to 4.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Confirmed Investigator Determined PFS According to RECIST v1.1

End point title	Part B: Confirmed Investigator Determined PFS According to RECIST v1.1 ^[21]
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End point description:

PFS: time from start of treatment to 1st documentation of PD by RECIST v1.1. Participants who do not have PD, are still on study at time of analysis/removed from study prior to documentation of PD were censored at date of last disease assessment documenting absence of PD. Participants who started new anticancer treatment prior to documentation of PD were censored at date of last disease assessment prior to start of new treatment. PD: at least 20% increase in sum of diameters of target lesions, taking as reference smallest sum on study. Sum must also demonstrate absolute increase of at least 0.5 cm. Appearance of one or more new lesions was also considered progression. Median was estimated using Kaplan-Meier method and CI was calculated using complementary log-log transformation method. FAS: all participants who received any amount of study drug. 'N'= participants evaluable for endpoint. 77777= insufficient number of participants with events to calculate upper limit of 95% CI.

End point type	Secondary
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End point timeframe:

From first dose of study treatment to the date of PD or clinical PD or censoring whichever occurred first (maximum up to 34.7 months for 1.25 mg/kg and 5.7 months for 1 mg/kg dose level)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	19	14
Units: Months				
median (confidence interval 95%)	1.4 (1.18 to 2.04)	1.8 (1.12 to 5.72)	2.4 (1.31 to 2.96)	2.7 (1.18 to 2.86)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	13	30
Units: Months				
median (confidence interval 95%)	2.8 (1.38 to 3.32)	2.3 (1.25 to 2.73)	4.9 (2.10 to 5.65)	4.2 (2.50 to 6.97)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	2
Units: Months				
median (confidence interval 95%)	1.9 (1.02 to 77777)	1.3 (-77777 to 77777)	1.5 (1.35 to 77777)	4.2 (2.76 to 77777)

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Confirmed Investigator Determined PSA-PFS, for Prostate Cancer

End point title	Part B: Confirmed Investigator Determined PSA-PFS, for Prostate Cancer ^[22]
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End point description:

PSA-PFS: time from start of treatment to 1st documentation of PSA progression/death due to any cause, whichever occurred 1st. Participants who don't have PD, are still on study at time of analysis/removed from study prior to documentation of PD was censored at date of last disease assessment documenting absence of PD. Participants who started new anticancer treatment prior to documentation of PD were censored at date of last disease assessment prior to start of new treatment. PD: at least 20% increase in sum of diameters of target lesions, taking as reference smallest sum on study. Sum must also demonstrate absolute increase of 0.5cm. Appearance of 1 or more new lesions was considered progression. Median was estimated using Kaplan-Meier; CI was calculated using complementary log-log transformation. FAS: participants who received any amount of study drug. As prespecified in protocol, endpoint planned to be analysed only in Part B: Cohort 7, LV 1.25mg/kg arm. 'N'=participants evaluable for endpoint.

End point type	Secondary
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End point timeframe:

From first dose of study treatment to the date of PD or clinical PD or censoring whichever occurred first (maximum up to 5.7 months)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 7, LV 1.25 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Months				
median (confidence interval 95%)	3.7 (2.8 to 5.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Overall Survival (OS)

End point title	Part A: Overall Survival (OS) ^[23]
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End point description:

OS was defined as the time from the start of study treatment to date of death due to any cause. Participants who do not have PD and are still on study at the time of an analysis or who are removed from the study prior to documentation of PD was censored at the date of last disease assessment documenting absence of PD. Participants who started a new anticancer treatment prior to documentation of PD were censored at the date of last disease assessment prior to the start of new treatment. Median was estimated using the Kaplan-Meier method. The FAS included all participants who received any amount of study drug. 77777= insufficient number of participants with events to calculate the upper limit of the 95% confidence interval.

End point type	Secondary
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End point timeframe:

From first dose of study treatment to the date of death or censoring whichever occurred first (maximum up to 27.5 months)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	13	7
Units: Months				
median (confidence interval 95%)	6.1 (1.38 to 15.84)	2.5 (1.74 to 77777)	6.5 (2.20 to 16.95)	4.8 (0.33 to 6.97)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Months				
median (confidence interval 95%)	7.2 (0.59 to 77777)	8.7 (3.98 to 77777)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Overall Survival

End point title	Part B: Overall Survival ^[24]
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End point description:

OS was defined as the time from the start of study treatment to date of death due to any cause. Participants who do not have PD and are still on study at the time of an analysis or who are removed from the study prior to documentation of PD was censored at the date of last disease assessment documenting absence of PD. Participants who started a new anticancer treatment prior to documentation of PD were censored at the date of last disease assessment prior to the start of new treatment. Median was estimated using the Kaplan-Meier method. The FAS included all participants who received any amount of study drug. 77777= insufficient number of participants with events to calculate the upper limit of the 95% confidence interval.

End point type	Secondary
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End point timeframe:

From first dose of study treatment to the date of death or censoring whichever occurred first (maximum up to 37.5 months for 1.25 mg/kg and 20.9 months for 1 mg/kg dose level)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	19	14
Units: Months				
median (confidence interval 95%)	4.7 (3.45 to 8.74)	9.0 (4.53 to 12.68)	9.3 (2.92 to 20.14)	5.2 (3.42 to 18.33)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	13	30
Units: Months				
median (confidence interval 95%)	12.7 (4.17 to 15.28)	3.8 (1.77 to 8.61)	10.1 (6.47 to 77777)	11.5 (9.26 to 15.41)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	2
Units: Months				
median (confidence interval 95%)	11.1 (1.22 to 77777)	77777 (1.71 to 77777)	5.6 (1.64 to 77777)	14.2 (8.34 to 77777)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Maximum Serum Concentration (Cmax) According to Antibody-Drug Conjugate (ADC) Pharmacokinetic Parameters

End point title	Part A: Maximum Serum Concentration (Cmax) According to Antibody-Drug Conjugate (ADC) Pharmacokinetic Parameters ^[25]
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End point description:

Cmax according to ADC pharmacokinetic parameters was reported. The safety analysis set included all participants who received any amount of study drug.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr, 168hr and 336hr post dose of Cycle 1 (each cycle = 21 days)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	13	7
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	50.4 (± 31.2)	58.6 (± 1.0)	55.8 (± 29.6)	52.3 (± 23.6)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	39.6 (± 14.7)	55.2 (± 64.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Area Under the Serum Concentration Time Curve Between Days 0 to 21 (AUC21) of Ladiratuzumab Vedotin

End point title	Part A: Area Under the Serum Concentration Time Curve Between Days 0 to 21 (AUC21) of Ladiratuzumab Vedotin ^[26]
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End point description:

Area under the observed concentration-time curve from the time of dosing to Day 21 of LV was calculated by noncompartmental analysis. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed (N)' signifies participants evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr, 168hr and 336hr post dose of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	11	6
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	142.5 (± 18.9)	175.6 (± 16.5)	145.3 (± 35.1)	146.6 (± 28.3)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	123.2 (± 21.7)	132.0 (± 26.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: AUC21 of Total Antibody (TAB)

End point title	Part A: AUC21 of Total Antibody (TAB) ^[27]
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End point description:

Area under the observed concentration-time curve from the time of dosing to Day 21 of TAB was calculated by noncompartmental analysis. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr, 168hr and 336hr post dose of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	10	6
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	302.4 (± 19.7)	328.5 (± 17.8)	280.3 (± 34.1)	292.3 (± 28.2)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	10		
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	219.8 (± 28.5)	258.9 (± 31.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Cmax According to TAB Pharmacokinetic Parameters

End point title	Part A: Cmax According to TAB Pharmacokinetic Parameters ^[28]
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End point description:

Cmax according to TAB pharmacokinetic parameters was reported. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr, 168hr and 336hr post dose of Cycle 1 (each cycle = 21 days)

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: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	2	11	7
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	61.6 (± 23.7)	66.1 (± 20.8)	68.2 (± 30.5)	61.4 (± 16.1)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	10		
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	50.7 (± 38.3)	57.2 (± 24.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Cmax According to MMAE Pharmacokinetic Parameters

End point title	Part A: Cmax According to MMAE Pharmacokinetic
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End point description:

Cmax according to MMAE pharmacokinetic parameters was reported. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. 77777= insufficient number of participants to calculate the geometric coefficient of variation.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr, 168hr and 336hr post dose of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	7	2
Units: Nanogram per millilitre				
geometric mean (geometric coefficient of variation)	2.8 (± 15.7)	5.7 (± 77777)	6.4 (± 83.1)	6.3 (± 10.6)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	6		
Units: Nanogram per millilitre				
geometric mean (geometric coefficient of variation)	11.3 (± 12.6)	3.6 (± 41.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: AUC21 of Monomethyl Auristatin E (MMAE)

End point title	Part A: AUC21 of Monomethyl Auristatin E (MMAE) ^[30]
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End point description:

Area under the observed concentration-time curve from the time of dosing to Day 21 of MMAE was calculated by noncompartmental analysis. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. 77777= insufficient number of participants to calculate the geometric coefficient of variation.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr, 168hr and 336hr post dose of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	7	3
Units: Day*nanogram per milliliter				
geometric mean (geometric coefficient of variation)	34.1 (± 21.1)	50.5 (± 77777)	62.9 (± 79.3)	66.2 (± 45.6)

End point values	Part A: Cohort 5, LV 2.5 mg/kg	Part A: Cohort 6, LV 2.5 mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	7		
Units: Day*nanogram per milliliter				
geometric mean (geometric coefficient of variation)	91.0 (± 19.3)	35.2 (± 36.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Area Under the Concentration Time Curve Between Day 0 to 7 (AUC7) of ADC

End point title	Part B: Area Under the Concentration Time Curve Between Day 0 to 7 (AUC7) of ADC ^[31]
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End point description:

Area under the observed concentration-time curve from the time of dosing to Day 7 of ADC was calculated by noncompartmental analysis. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. 77777= insufficient number of participants to calculate the geometric coefficient of variation. There were insufficient samples to provide pharmacokinetic (PK) estimates for analytes in Part B: Cohort 6, LV 1.0 mg/kg arm.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr post-dose, and pre-dose on day 8 of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	11	18	9
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	57.3 (± 23.2)	51.7 (± 16.9)	59.5 (± 29.7)	60.6 (± 36.7)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	11	25
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	43.3 (± 12.6)	50.7 (± 27.2)	66.0 (± 42.8)	46.8 (± 25.0)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	0 ^[32]
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	42.1 (± 0.5)	52.0 (± 0.1)	44.8 (± 77777)	()

Notes:

[32] - There were insufficient samples to provide PK estimates for analytes for this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Cmax According to ADC Pharmacokinetic Parameters

End point title	Part B: Cmax According to ADC Pharmacokinetic Parameters ^[33]
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End point description:

Cmax according to ADC pharmacokinetic parameters was reported. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. There were insufficient samples to provide PK estimates for analytes in Part B: Cohort 6, LV 1.0 mg/kg arm.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr post-dose and pre-dose and end of infusion on day 8 and 15 of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	14	19	14
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	35.3 (± 35.0)	27.8 (± 19.7)	30.9 (± 19.2)	28.7 (± 28.6)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	18	12	27
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	25.0 (± 28.8)	28.0 (± 17.2)	30.5 (± 15.1)	25.4 (± 21.9)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	0 ^[34]
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	29.5 (± 20.3)	24.3 (± 10.2)	24.1 (± 6.2)	()

Notes:

[34] - There were insufficient samples to provide PK estimates for analytes in this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUC7 of TAB

End point title	Part B: AUC7 of TAB ^[35]
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End point description:

Area under the observed concentration-time curve from the time of dosing to Day 7 of TAB was calculated by noncompartmental analysis. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. 77777= insufficient number of participants to calculate the geometric coefficient of variation. There were insufficient samples to provide PK estimates for analytes in Part B: Cohort 6, LV 1.0 mg/kg arm.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr post dose and pre-dose and end of infusion on day 8 and 15 of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	11	18	9
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	101.1 (± 29.4)	92.7 (± 18.7)	106.9 (± 29.8)	91.2 (± 30.9)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	11	25
Units: Day*micrograms per millilitre				

geometric mean (geometric coefficient of variation)	73.9 (± 20.7)	85.7 (± 26.0)	106.5 (± 28.2)	74.7 (± 26.3)
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End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	0 ^[36]
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	76.6 (± 22.6)	88.6 (± 11.1)	71.4 (± 77777)	()

Notes:

[36] - There were insufficient samples to provide PK estimates for analytes in this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Cmax According to TAB Pharmacokinetic Parameters

End point title	Part B: Cmax According to TAB Pharmacokinetic Parameters ^[37]
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End point description:

Cmax according to TAB pharmacokinetic parameters was reported. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. There were insufficient samples to provide PK estimates for analytes in Part B: Cohort 6, LV 1.0 mg/kg arm.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr post-dose and pre-dose and end of infusion on day 8 and 15 of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	14	19	14
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	38.3 (± 17.9)	31.6 (± 16.6)	36.8 (± 21.8)	32.1 (± 26.2)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	17	12	29
Units: Micrograms per millilitre				

geometric mean (geometric coefficient of variation)	27.4 (± 28.9)	31.3 (± 19.7)	32.6 (± 25.9)	32.5 (± 73.8)
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End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	0 ^[38]
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)	26.8 (± 15.6)	30.6 (± 14.8)	27.9 (± 2.0)	()

Notes:

[38] - There were insufficient samples to provide PK estimates for analytes in this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: AUC7 OF MMAE

End point title	Part B: AUC7 OF MMAE ^[39]
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End point description:

Area under the observed concentration-time curve from the time of dosing to Day 7 of MMAE was calculated by noncompartmental analysis. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. 77777= insufficient number of participants to calculate the geometric coefficient of variation. There were insufficient samples to provide PK estimates for analytes in Part B: Cohort 6, LV 1.0 mg/kg arm.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr post-dose and pre-dose and end of infusion on day 8 and 15 of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	11	18	9
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	14.6 (± 63.1)	16.5 (± 55.6)	11.9 (± 51.5)	15.6 (± 51.0)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	12	11	25

Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	17.3 (± 67.6)	13.7 (± 83.0)	10.7 (± 57.3)	13.8 (± 45.2)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	0 ^[40]
Units: Day*micrograms per millilitre				
geometric mean (geometric coefficient of variation)	10.8 (± 64.1)	12.4 (± 25.9)	8.5 (± 77777)	()

Notes:

[40] - There were insufficient samples to provide PK estimates for analytes in this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Cmax According to MMAE Pharmacokinetic Parameters

End point title	Part B: Cmax According to MMAE Pharmacokinetic
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End point description:

Cmax according to MMAE pharmacokinetic parameters was reported. The safety analysis set included all participants who received any amount of study drug. Here, 'Number of Participants Analysed' signifies participants evaluable for this endpoint. 77777= insufficient number of participants to calculate the geometric coefficient of variation. There were insufficient samples to provide PK estimates for analytes in Part B: Cohort 3, LV 1.0 mg/kg and Part B: Cohort 6, LV 1.0 mg/kg arm.

End point type	Secondary
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End point timeframe:

Pre-dose, end of infusion, 2hr, 4hr, 48hr post-dose and pre-dose and end of infusion on day 8 and 15 of Cycle 1 (each cycle = 21 days)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	4	8	8
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)	2.8 (± 60.7)	4.5 (± 50.4)	2.6 (± 59.1)	2.7 (± 39.9)

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	11	8	16
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)	3.3 (\pm 65.8)	2.9 (\pm 114.9)	1.7 (\pm 28.9)	2.4 (\pm 52.7)

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0 ^[42]	1	0 ^[43]
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)	1.4 (\pm 77777)	()	1.7 (\pm 77777)	()

Notes:

[42] - There were insufficient samples to provide PK estimates for analytes in this arm.

[43] - There were insufficient samples to provide PK estimates for analytes in this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Part A: Number of Participants With Positive Post-Baseline Antitherapeutic Antibody (ATA) Incidence

End point title	Part A: Number of Participants With Positive Post-Baseline Antitherapeutic Antibody (ATA) Incidence ^[44]
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End point description:

A positive baseline ATA result was considered positive post-baseline if the post-baseline ATA titer result was at least four times higher than the baseline result. The safety analysis set included all participants who received any amount of study drug.

End point type	Secondary
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End point timeframe:

Anytime during study (maximum up to 8.8 months)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part A: Cohort 1, LV 2.5 mg/kg	Part A: Cohort 2, LV 2.5 mg/kg	Part A: Cohort 3, LV 2.5 mg/kg	Part A: Cohort 4, LV 2.5 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	2	13	7
Units: Participants				
Baseline Negative Positive post-baseline	1	0	1	1
Baseline Positive Positive post-baseline	0	0	0	0

End point values	Part A: Cohort 5, LV 2.5	Part A: Cohort 6, LV 2.5		
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	mg/kg	mg/kg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	12		
Units: Participants				
Baseline Negative Positive post-baseline	0	1		
Baseline Positive Positive post-baseline	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Number of Participants With Positive Post-Baseline ATA Incidence

End point title	Part B: Number of Participants With Positive Post-Baseline ATA Incidence ^[45]
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End point description:

A positive baseline ATA result was considered positive post-baseline if the post-baseline ATA titer result was at least four times higher than the baseline result. The safety analysis set included all participants who received any amount of study drug.

End point type	Secondary
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End point timeframe:

Anytime during study (maximum up to 22.1 months for 1.25 mg/kg and 5.1 months for 1 mg/kg)

Notes:

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

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Part B: Cohort 1, LV 1.25 mg/kg	Part B: Cohort 2, LV 1.25 mg/kg	Part B: Cohort 3, LV 1.25 mg/kg	Part B: Cohort 4, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	19	14
Units: Participants				
Baseline Negative Positive post-baseline	1	1	4	0
Baseline Positive Positive post-baseline	0	1	0	0

End point values	Part B: Cohort 5, LV 1.25 mg/kg	Part B: Cohort 6, LV 1.25 mg/kg	Part B: Cohort 7, LV 1.25 mg/kg	Part B: Cohort 8, LV 1.25 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	13	30
Units: Participants				
Baseline Negative Positive post-baseline	2	1	1	4
Baseline Positive Positive post-baseline	0	0	0	0

End point values	Part B: Cohort 1, LV 1.0 mg/kg	Part B: Cohort 3, LV 1.0 mg/kg	Part B: Cohort 4, LV 1.0 mg/kg	Part B: Cohort 6, LV 1.0 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	2
Units: Participants				
Baseline Negative Positive post-baseline	0	2	0	0
Baseline Positive Positive post-baseline	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study treatment up to 30 days after last dose of study treatment (maximum up to 37.5 months)

Adverse event reporting additional description:

Same event may appear as both AE and SAE. What is presented are distinct events. Event may be categorised as serious in one participant and non-serious in another, or participant may have experienced both serious and non-serious event. All-cause mortality included all enrolled participants. SAEs and non-SAEs were analysed in safety analysis set.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	v26.1
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Reporting groups

Reporting group title	Part A 2.5 mg/kg: Esophageal-squamous
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Reporting group description:

Part A 2.5 mg/kg: Esophageal-squamous

Reporting group title	Part A 2.5 mg/kg: HNSCC
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Reporting group description:

Part A 2.5 mg/kg: HNSCC

Reporting group title	Part A 2.5 mg/kg: NSCLC-nonsquamous
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Reporting group description:

Part A 2.5 mg/kg: NSCLC-nonsquamous

Reporting group title	Part A 2.5 mg/kg: NSCLC-squamous
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Reporting group description:

Part A 2.5 mg/kg: NSCLC-squamous

Reporting group title	Part A 2.5 mg/kg: SCLC
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Reporting group description:

Part A 2.5 mg/kg: SCLC

Reporting group title	Part A 2.5 mg/kg: Gastric and GEJ
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Reporting group description:

Part A 2.5 mg/kg: Gastric and GEJ

Reporting group title	Part B 1.25 mg/kg: Prostate Cancer
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Reporting group description:

Part B 1.25 mg/kg: Prostate Cancer

Reporting group title	Part B 1.25 mg/kg: Melanoma
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Reporting group description:

Part B 1.25 mg/kg: Melanoma

Reporting group title	Part B 1.0 mg/kg: SCLC
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Reporting group description:

Part B 1.0 mg/kg: SCLC

Reporting group title	Part B 1.0 mg/kg: NSCLC-nonsquamous
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Reporting group description:

Part B 1.0 mg/kg: NSCLC-nonsquamous

Reporting group title	Part B 1.0 mg/kg: HNSCC
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Reporting group description:

Part B 1.0 mg/kg: HNSCC

Reporting group title	Part B 1.25 mg/kg: Gastric and GEJ
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Reporting group description:

Part B 1.25 mg/kg: Gastric and GEJ

Reporting group title	Part B 1.25 mg/kg: Esophageal-squamous
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Reporting group description:

Part B 1.25 mg/kg: Esophageal-squamous

Reporting group title	Part B 1.25 mg/kg: HNSCC
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Reporting group description:

Part B 1.25 mg/kg: HNSCC

Reporting group title	Part B 1.0 mg/kg: Gastric and GEJ
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Reporting group description:

Part B 1.0 mg/kg: Gastric and GEJ

Reporting group title	Part B 1.25 mg/kg: NSCLC-squamous
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Reporting group description:

Part B 1.25 mg/kg: NSCLC-squamous

Reporting group title	Part B 1.25 mg/kg: SCLC
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Reporting group description:

Part B 1.25 mg/kg: SCLC

Reporting group title	Part B 1.25 mg/kg: NSCLC-nonsquamous
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Reporting group description:

Part B 1.25 mg/kg: NSCLC-nonsquamous

Serious adverse events	Part A 2.5 mg/kg: Esophageal- squamous	Part A 2.5 mg/kg: HNSCC	Part A 2.5 mg/kg: NSCLC- nonsquamous
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	2 / 7 (28.57%)	7 / 13 (53.85%)
number of deaths (all causes)	4	7	10
number of deaths resulting from adverse events	1	0	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 distress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 failure			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Investigations			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Laryngocele			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Petit mal epilepsy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vocal cord paralysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Neutropenia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
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 lower			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 perforation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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			
Arthritis bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
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	Part A 2.5 mg/kg: NSCLC-squamous	Part A 2.5 mg/kg: SCLC	Part A 2.5 mg/kg: Gastric and GEJ
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	5 / 10 (50.00%)	3 / 12 (25.00%)
number of deaths (all causes)	2	9	5
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	3 / 12 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 4
Complication associated with device			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 2 (50.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Productive cough			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 2 (50.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Overdose			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Laryngocele			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Acute motor-sensory axonal neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Abdominal pain lower			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 10 (20.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	2 / 2	0 / 0
Mobility decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Serious adverse events	Part B 1.25 mg/kg:	Part B 1.25 mg/kg:	Part B 1.0 mg/kg:
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	Prostate Cancer	Melanoma	SCLC
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 13 (30.77%)	10 / 30 (33.33%)	1 / 2 (50.00%)
number of deaths (all causes)	7	16	2
number of deaths resulting from adverse events	1	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Complication associated with device			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (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
Oedema peripheral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchial obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Productive cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 distress			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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			
Mental status changes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Neutrophil count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Laryngocele			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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			
Acute myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Atrial fibrillation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (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
Cardiac arrest			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Pericardial effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (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 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Encephalopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 lower			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Stomatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 perforation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (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
Back pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Myalgia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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			
Arthritis bacterial			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Biliary sepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Device related infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (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
Staphylococcal infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 sepsis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
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	Part B 1.0 mg/kg: NSCLC- nonsquamous	Part B 1.0 mg/kg: HNSCC	Part B 1.25 mg/kg: Gastric and GEJ
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	1 / 2 (50.00%)	12 / 21 (57.14%)
number of deaths (all causes)	1	2	13
number of deaths resulting from	1	0	2

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Complication associated with device			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 distress			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 failure			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Laryngocele			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
Acute myocardial infarction			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 21 (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
Dizziness			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 21 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	1 / 2 (50.00%)	3 / 21 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Abdominal pain lower			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	1 / 2 (50.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (50.00%)	0 / 2 (0.00%)	0 / 21 (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	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nausea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oesophageal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
Arthritis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Biliary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 21 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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			
Decreased appetite			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
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	Part B 1.25 mg/kg: Esophageal- squamous	Part B 1.25 mg/kg: HNSCC	Part B 1.0 mg/kg: Gastric and GEJ
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 17 (52.94%)	8 / 14 (57.14%)	0 / 2 (0.00%)
number of deaths (all causes)	12	12	2
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			

subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (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

Oropharyngeal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pneumonitis			
subjects affected / exposed	2 / 17 (11.76%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 distress			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			

Mental status changes			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Laryngocele			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			
Acute myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Syncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Blood and lymphatic system disorders			
Febrile neutropenia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 lower			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Diarrhoea			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal pain			

subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Oesophageal fistula			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 perforation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			
Arthritis bacterial			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			

subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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
Pneumonia			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
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 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (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

Serious adverse events	Part B 1.25 mg/kg: NSCLC-squamous	Part B 1.25 mg/kg: SCLC	Part B 1.25 mg/kg: NSCLC- nonsquamous
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 16 (31.25%)	6 / 16 (37.50%)	9 / 19 (47.37%)
number of deaths (all causes)	13	13	14
number of deaths resulting from adverse events	1	0	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			
Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 peripheral			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Interstitial lung disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory distress			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory failure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			
Mental status changes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			

Brain natriuretic peptide increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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%)	1 / 16 (6.25%)	0 / 19 (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
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Congenital, familial and genetic disorders			
Laryngocele			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			
Acute myocardial infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Myocardial infarction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhage intracranial			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (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
Spinal cord compression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Anaemia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Abdominal pain lower			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (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
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
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	1 / 16 (6.25%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ileus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
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%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oesophageal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal fistula			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Skin and subcutaneous tissue disorders			
Erythema multiforme			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			

Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adrenal insufficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Pneumonia aspiration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
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			
Decreased appetite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 2	1 / 1
Hyperglycaemia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

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

Non-serious adverse events	Part A 2.5 mg/kg: Esophageal- squamous	Part A 2.5 mg/kg: HNSCC	Part A 2.5 mg/kg: NSCLC- nonsquamous
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	6 / 7 (85.71%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Arterial occlusive disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Raynaud's phenomenon			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	2 / 13 (15.38%)
occurrences (all)	0	2	2
Fatigue			
subjects affected / exposed	2 / 5 (40.00%)	5 / 7 (71.43%)	10 / 13 (76.92%)
occurrences (all)	2	5	10
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Face oedema			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Injection site irritation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Swelling face			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Swelling			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 5 (40.00%)	0 / 7 (0.00%)	4 / 13 (30.77%)
occurrences (all)	2	0	4
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Haemothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Laryngeal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Laryngeal ventricle prolapse			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	2 / 5 (40.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 7 (14.29%)	2 / 13 (15.38%)
occurrences (all)	2	1	2
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	3 / 13 (23.08%)
occurrences (all)	1	1	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Blood magnesium decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Iron binding capacity total decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Injury, poisoning and procedural complications			
Burns first degree			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Craniocerebral injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Atrial fibrillation			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	1 / 13 (7.69%)
occurrences (all)	1	1	2
Disturbance in attention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 5 (40.00%)	1 / 7 (14.29%)	3 / 13 (23.08%)
occurrences (all)	2	1	3
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Amnesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Asterixis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dizziness postural			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1

Dysarthria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypogeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1

Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	2 / 13 (15.38%)
occurrences (all)	1	1	2
Neutropenia			
subjects affected / exposed	3 / 5 (60.00%)	1 / 7 (14.29%)	1 / 13 (7.69%)
occurrences (all)	4	2	1
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Anaemia macrocytic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			

Tinnitus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	2 / 7 (28.57%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	2 / 5 (40.00%)	1 / 7 (14.29%)	4 / 13 (30.77%)
occurrences (all)	2	2	4
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	3 / 7 (42.86%)	6 / 13 (46.15%)
occurrences (all)	2	3	9
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 5 (20.00%)	3 / 7 (42.86%)	8 / 13 (61.54%)
occurrences (all)	1	3	10
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	2
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	4 / 13 (30.77%)
occurrences (all)	1	1	7
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Swollen tongue			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	1 / 13 (7.69%)
occurrences (all)	0	1	4
Tongue ulceration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	1 / 5 (20.00%)	4 / 7 (57.14%)	5 / 13 (38.46%)
occurrences (all)	1	4	5
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Pruritus			
subjects affected / exposed	1 / 5 (20.00%)	1 / 7 (14.29%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Dermatitis acneiform			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Rash papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin maceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Skin toxicity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			

subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Androgen deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 7 (28.57%)	2 / 13 (15.38%)
occurrences (all)	1	2	2
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	2 / 5 (40.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Soft tissue necrosis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Conjunctivitis bacterial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymphangitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Pneumonia aspiration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 7 (14.29%) 1	0 / 13 (0.00%) 0
Rash pustular subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Tooth infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Tooth abscess subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Sputum purulent subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Metabolism and nutrition disorders			
Dehydration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	2 / 7 (28.57%) 2	4 / 13 (30.77%) 4
Decreased appetite subjects affected / exposed occurrences (all)	3 / 5 (60.00%) 3	4 / 7 (57.14%) 5	6 / 13 (46.15%) 6
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	0 / 13 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 7 (0.00%) 0	1 / 13 (7.69%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 7 (0.00%) 0	4 / 13 (30.77%) 5
Hypomagnesaemia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	4 / 13 (30.77%)
occurrences (all)	1	0	4
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Abnormal loss of weight			
subjects affected / exposed	0 / 5 (0.00%)	1 / 7 (14.29%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Cachexia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hypercreatininaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	0 / 5 (0.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 7 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part A 2.5 mg/kg: NSCLC-squamous	Part A 2.5 mg/kg: SCLC	Part A 2.5 mg/kg: Gastric and GEJ
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	10 / 10 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	2 / 10 (20.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Arterial occlusive disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 2 (50.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 10 (10.00%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	2 / 12 (16.67%)
occurrences (all)	0	1	2

Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injection site irritation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Swelling face subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Swelling subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Reproductive system and breast disorders Genital burning sensation subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	3 / 10 (30.00%) 3	1 / 12 (8.33%) 2
Haemoptysis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Productive cough subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 10 (10.00%) 1	2 / 12 (16.67%) 2
Cough subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	2 / 10 (20.00%) 2	0 / 12 (0.00%) 0
Pulmonary embolism subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngeal ventricle prolapse			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Depression			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Poor quality sleep			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron binding capacity total decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Burns first degree			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Craniocerebral injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 2 (50.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 2 (0.00%)	2 / 10 (20.00%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	3 / 12 (25.00%)
occurrences (all)	0	3	3
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Amnesia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asterixis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypogeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	3
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 10 (20.00%)	4 / 12 (33.33%)
occurrences (all)	0	2	6
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Leukopenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 10 (10.00%) 1	0 / 12 (0.00%) 0
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Anaemia macrocytic subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Eye disorders Cataract subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	3 / 10 (30.00%) 3	4 / 12 (33.33%) 5
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 10 (0.00%) 0	2 / 12 (16.67%) 2
Constipation subjects affected / exposed occurrences (all)	2 / 2 (100.00%) 2	2 / 10 (20.00%) 2	4 / 12 (33.33%) 4
Diarrhoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	4 / 12 (33.33%)
occurrences (all)	0	0	4
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	3 / 10 (30.00%)	3 / 12 (25.00%)
occurrences (all)	1	6	4
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	2 / 10 (20.00%)	1 / 12 (8.33%)
occurrences (all)	0	3	1
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 2 (50.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

Hypertransaminasaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 10 (30.00%)	7 / 12 (58.33%)
occurrences (all)	0	3	7
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 2 (50.00%)	2 / 10 (20.00%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin maceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	4
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Androgen deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hyperprolactinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Soft tissue necrosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Escherichia infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Sputum purulent			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 2 (50.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Decreased appetite			

subjects affected / exposed	0 / 2 (0.00%)	3 / 10 (30.00%)	2 / 12 (16.67%)
occurrences (all)	0	3	2
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 10 (20.00%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Hypokalaemia			
subjects affected / exposed	1 / 2 (50.00%)	3 / 10 (30.00%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 10 (10.00%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Abnormal loss of weight			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hypoalbuminaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 10 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B 1.25 mg/kg: Prostate Cancer	Part B 1.25 mg/kg: Melanoma	Part B 1.0 mg/kg: SCLC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	30 / 30 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Arterial occlusive disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypertension			

subjects affected / exposed	0 / 13 (0.00%)	3 / 30 (10.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 13 (15.38%)	4 / 30 (13.33%)	1 / 2 (50.00%)
occurrences (all)	2	6	1
Fatigue			
subjects affected / exposed	7 / 13 (53.85%)	13 / 30 (43.33%)	1 / 2 (50.00%)
occurrences (all)	8	18	1
Oedema peripheral			
subjects affected / exposed	1 / 13 (7.69%)	3 / 30 (10.00%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	3 / 30 (10.00%)	0 / 2 (0.00%)
occurrences (all)	0	7	0
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Face oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site irritation			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Oedema			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 13 (23.08%)	1 / 30 (3.33%)	2 / 2 (100.00%)
occurrences (all)	3	1	2
Haemoptysis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 13 (7.69%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Haemothorax			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Laryngeal inflammation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngeal ventricle prolapse			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	2 / 13 (15.38%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Insomnia			
subjects affected / exposed	4 / 13 (30.77%)	6 / 30 (20.00%)	0 / 2 (0.00%)
occurrences (all)	5	6	0
Depression			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 13 (23.08%)	8 / 30 (26.67%)	0 / 2 (0.00%)
occurrences (all)	3	11	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 13 (15.38%)	10 / 30 (33.33%)	0 / 2 (0.00%)
occurrences (all)	3	11	0
Weight decreased			
subjects affected / exposed	0 / 13 (0.00%)	7 / 30 (23.33%)	0 / 2 (0.00%)
occurrences (all)	0	8	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Blood magnesium decreased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron binding capacity total decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Burns first degree			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Craniocerebral injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Atrial fibrillation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 13 (0.00%)	4 / 30 (13.33%)	1 / 2 (50.00%)
occurrences (all)	0	6	1
Dizziness			
subjects affected / exposed	2 / 13 (15.38%)	1 / 30 (3.33%)	1 / 2 (50.00%)
occurrences (all)	2	2	1
Disturbance in attention			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 13 (23.08%)	15 / 30 (50.00%)	0 / 2 (0.00%)
occurrences (all)	4	17	0
Paraesthesia			
subjects affected / exposed	2 / 13 (15.38%)	4 / 30 (13.33%)	0 / 2 (0.00%)
occurrences (all)	2	6	0
Amnesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Asterixis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dysarthria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypogeusia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			

subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lumbar radiculopathy			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Neurotoxicity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 13 (7.69%)	7 / 30 (23.33%)	0 / 2 (0.00%)
occurrences (all)	1	8	0
Neutropenia			
subjects affected / exposed	5 / 13 (38.46%)	8 / 30 (26.67%)	0 / 2 (0.00%)
occurrences (all)	8	10	0
Leukocytosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Leukopenia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anaemia macrocytic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual impairment			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 13 (15.38%)	8 / 30 (26.67%)	0 / 2 (0.00%)
occurrences (all)	4	10	0
Abdominal pain upper			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Constipation			
subjects affected / exposed	4 / 13 (30.77%)	13 / 30 (43.33%)	0 / 2 (0.00%)
occurrences (all)	6	13	0
Diarrhoea			
subjects affected / exposed	4 / 13 (30.77%)	14 / 30 (46.67%)	1 / 2 (50.00%)
occurrences (all)	6	24	1
Dyspepsia			
subjects affected / exposed	2 / 13 (15.38%)	3 / 30 (10.00%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Gastrointestinal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 13 (30.77%)	16 / 30 (53.33%)	1 / 2 (50.00%)
occurrences (all)	4	22	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Stomatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	8 / 30 (26.67%)	0 / 2 (0.00%)
occurrences (all)	0	8	0
Abdominal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Abdominal distension			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Ascites			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Hiatus hernia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Odynophagia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Oesophagitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Oral pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Tongue ulceration subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Hepatobiliary disorders Hypertransaminaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Jaundice subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	4 / 13 (30.77%) 4	17 / 30 (56.67%) 18	0 / 2 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 30 (3.33%) 1	0 / 2 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	4 / 30 (13.33%) 7	0 / 2 (0.00%) 0
Dermatitis acneiform			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Rash maculo-papular			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	2 / 13 (15.38%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Erythema multiforme			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin maceration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Skin ulcer			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Haematuria			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Androgen deficiency subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 30 (3.33%) 1	0 / 2 (0.00%) 0
Hyperprolactinaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	5 / 30 (16.67%) 6	1 / 2 (50.00%) 1
Back pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	6 / 30 (20.00%) 6	0 / 2 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 3	1 / 30 (3.33%) 2	0 / 2 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	5 / 30 (16.67%) 10	1 / 2 (50.00%) 1
Pain in extremity subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	3 / 30 (10.00%) 4	0 / 2 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 30 (3.33%) 1	1 / 2 (50.00%) 1
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Muscle spasms			

subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Soft tissue necrosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis bacterial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 13 (7.69%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	3 / 30 (10.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphangitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 13 (0.00%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	2 / 13 (15.38%)	1 / 30 (3.33%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Tooth infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Tooth abscess subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Sputum purulent subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Metabolism and nutrition disorders			
Dehydration subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	1 / 30 (3.33%) 1	0 / 2 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	6 / 13 (46.15%) 6	11 / 30 (36.67%) 12	1 / 2 (50.00%) 1
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	6 / 30 (20.00%) 9	0 / 2 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 3	1 / 30 (3.33%) 1	0 / 2 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 30 (3.33%) 1	1 / 2 (50.00%) 1
Abnormal loss of weight subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 30 (0.00%) 0	0 / 2 (0.00%) 0
Cachexia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 13 (0.00%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 30 (6.67%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hypocalcaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 30 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part B 1.0 mg/kg: NSCLC- nonsquamous	Part B 1.0 mg/kg: HNSCC	Part B 1.25 mg/kg: Gastric and GEJ
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 2 (100.00%)	19 / 21 (90.48%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Arterial occlusive disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Raynaud's phenomenon			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	11 / 21 (52.38%)
occurrences (all)	0	0	12
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injection site irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Reproductive system and breast disorders Genital burning sensation subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 21 (4.76%) 1
Haemoptysis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	0 / 21 (0.00%) 0
Productive cough subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 21 (4.76%) 1
Pulmonary embolism subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	1 / 21 (4.76%) 1
Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Aspiration subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0

Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haemothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Laryngeal ventricle prolapse			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Insomnia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	4 / 21 (19.05%)
occurrences (all)	1	0	4
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Weight decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	4 / 21 (19.05%)
occurrences (all)	1	0	4
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	3
Blood magnesium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Iron binding capacity total decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	5
Troponin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 21 (4.76%) 1
Injury, poisoning and procedural complications			
Burns first degree			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Craniocerebral injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Pericardial effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 21 (4.76%) 1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	7 / 21 (33.33%)
occurrences (all)	0	0	7
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Amnesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Asterixis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	3

Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypogeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	6 / 21 (28.57%)
occurrences (all)	0	1	8
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	3
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anaemia macrocytic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			

Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	6 / 21 (28.57%)
occurrences (all)	0	0	7
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	5 / 21 (23.81%)
occurrences (all)	0	0	6
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	8 / 21 (38.10%)
occurrences (all)	0	2	11
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Gastrointestinal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	9 / 21 (42.86%)
occurrences (all)	1	0	11
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	6 / 21 (28.57%)
occurrences (all)	1	0	6
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	7 / 21 (33.33%)
occurrences (all)	0	0	7
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Rash papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin maceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Micturition urgency			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Androgen deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Myalgia			

subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	1 / 21 (4.76%)
occurrences (all)	0	1	2
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Soft tissue necrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Musculoskeletal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Conjunctivitis bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lymphangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Pneumonia aspiration subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Rash pustular subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 21 (4.76%) 1
Tooth infection subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Tooth abscess subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Sputum purulent subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Metabolism and nutrition disorders			
Dehydration subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	0 / 21 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	8 / 21 (38.10%) 9
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 2	0 / 21 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 2 (0.00%) 0	1 / 21 (4.76%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	2 / 2 (100.00%) 3	0 / 2 (0.00%) 0	2 / 21 (9.52%) 2
Hypomagnesaemia			

subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
Abnormal loss of weight			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B 1.25 mg/kg: Esophageal- squamous	Part B 1.25 mg/kg: HNSCC	Part B 1.0 mg/kg: Gastric and GEJ
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 17 (100.00%)	14 / 14 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Arterial occlusive disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Fatigue			

subjects affected / exposed	12 / 17 (70.59%)	7 / 14 (50.00%)	1 / 2 (50.00%)
occurrences (all)	12	7	1
Oedema peripheral			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	2 / 17 (11.76%)	5 / 14 (35.71%)	1 / 2 (50.00%)
occurrences (all)	3	5	1
Chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site irritation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	2 / 14 (14.29%) 2	0 / 2 (0.00%) 0
Swelling face subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Swelling subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Reproductive system and breast disorders Genital burning sensation subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	3 / 17 (17.65%) 4	1 / 14 (7.14%) 1	0 / 2 (0.00%) 0
Haemoptysis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Productive cough subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	3 / 14 (21.43%) 3	0 / 2 (0.00%) 0
Pulmonary embolism subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Chronic obstructive pulmonary			

disease			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Dysphonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Haemothorax			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Laryngeal inflammation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngeal ventricle prolapse			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Pneumonitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	3 / 17 (17.65%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Depression			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hallucination			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Poor quality sleep			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			

Aspartate aminotransferase increased			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Weight decreased			
subjects affected / exposed	6 / 17 (35.29%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	6	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron binding capacity total decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Burns first degree			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Craniocerebral injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Sinus tachycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Dizziness			
subjects affected / exposed	2 / 17 (11.76%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Disturbance in attention			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 17 (17.65%)	8 / 14 (57.14%)	0 / 2 (0.00%)
occurrences (all)	3	8	0
Paraesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amnesia			

subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Asterixis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysarthria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypogeusia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			

subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Seizure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 17 (11.76%)	2 / 14 (14.29%)	1 / 2 (50.00%)
occurrences (all)	4	2	1
Neutropenia			
subjects affected / exposed	6 / 17 (35.29%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	8	3	0
Leukocytosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Leukopenia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	2 / 14 (14.29%) 2	0 / 2 (0.00%) 0
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Anaemia macrocytic subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Ear and labyrinth disorders Tinnitus subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Eye disorders Cataract subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	0 / 14 (0.00%) 0	0 / 2 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	4 / 17 (23.53%) 6	1 / 14 (7.14%) 1	0 / 2 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 14 (7.14%) 1	0 / 2 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	6 / 17 (35.29%) 8	3 / 14 (21.43%) 4	1 / 2 (50.00%) 1
Diarrhoea			

subjects affected / exposed	5 / 17 (29.41%)	5 / 14 (35.71%)	1 / 2 (50.00%)
occurrences (all)	7	5	2
Dyspepsia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	8 / 17 (47.06%)	6 / 14 (42.86%)	0 / 2 (0.00%)
occurrences (all)	9	7	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	3 / 17 (17.65%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Abdominal discomfort			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 17 (5.88%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Dysphagia			

subjects affected / exposed	2 / 17 (11.76%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Haematochezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hiatus hernia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Retching			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Odynophagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

Hypertransaminasaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	7 / 17 (41.18%)	4 / 14 (28.57%)	0 / 2 (0.00%)
occurrences (all)	7	4	0
Hyperhidrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 17 (0.00%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Pruritus			
subjects affected / exposed	3 / 17 (17.65%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Dermatitis acneiform			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin maceration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Acute kidney injury			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Androgen deficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 17 (11.76%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Back pain			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Muscular weakness			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 17 (5.88%)	3 / 14 (21.43%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Pain in extremity			
subjects affected / exposed	2 / 17 (11.76%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Soft tissue necrosis			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Conjunctivitis bacterial			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Pneumonia			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Rhinitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Escherichia infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphangitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash pustular			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sputum purulent			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Decreased appetite			

subjects affected / exposed	10 / 17 (58.82%)	6 / 14 (42.86%)	2 / 2 (100.00%)
occurrences (all)	12	6	2
Hypercalcaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	1 / 2 (50.00%)
occurrences (all)	1	4	1
Hypomagnesaemia			
subjects affected / exposed	1 / 17 (5.88%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Hyponatraemia			
subjects affected / exposed	2 / 17 (11.76%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Abnormal loss of weight			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			

subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B 1.25 mg/kg: NSCLC-squamous	Part B 1.25 mg/kg: SCLC	Part B 1.25 mg/kg: NSCLC- nonsquamous
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	15 / 16 (93.75%)	19 / 19 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	4
Arterial occlusive disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypertension			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Raynaud's phenomenon			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Fatigue			
subjects affected / exposed	9 / 16 (56.25%)	7 / 16 (43.75%)	12 / 19 (63.16%)
occurrences (all)	11	8	13
Oedema peripheral			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	3 / 19 (15.79%)
occurrences (all)	0	1	4
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	5 / 16 (31.25%)	2 / 19 (10.53%)
occurrences (all)	0	6	2
Chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Face oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Injection site irritation			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Genital burning sensation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	4 / 16 (25.00%)	4 / 16 (25.00%)	5 / 19 (26.32%)
occurrences (all)	4	5	5
Haemoptysis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Productive cough			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	2 / 19 (10.53%)
occurrences (all)	0	2	2
Cough			
subjects affected / exposed	2 / 16 (12.50%)	1 / 16 (6.25%)	4 / 19 (21.05%)
occurrences (all)	2	1	4
Pulmonary embolism			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Haemothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2

Laryngeal inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Laryngeal ventricle prolapse			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	1 / 19 (5.26%)
occurrences (all)	0	2	2
Pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	2 / 16 (12.50%)	3 / 19 (15.79%)
occurrences (all)	1	2	3
Depression			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Hallucination			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 16 (12.50%)	2 / 16 (12.50%)	1 / 19 (5.26%)
occurrences (all)	3	2	2
Alanine aminotransferase increased			
subjects affected / exposed	2 / 16 (12.50%)	2 / 16 (12.50%)	1 / 19 (5.26%)
occurrences (all)	2	2	1
Weight decreased			
subjects affected / exposed	0 / 16 (0.00%)	3 / 16 (18.75%)	3 / 19 (15.79%)
occurrences (all)	0	3	3
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Blood magnesium decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 16 (12.50%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	1
Iron binding capacity total decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	0 / 19 (0.00%)
occurrences (all)	0	4	0
Troponin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	1 / 19 (5.26%)
occurrences (all)	0	4	1
Injury, poisoning and procedural complications			
Burns first degree			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Infusion related reaction			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Fall subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	2 / 16 (12.50%) 2	2 / 19 (10.53%) 2
Craniocerebral injury subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Clavicle fracture subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 1	0 / 19 (0.00%) 0
Cardiac disorders Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Tachycardia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 1	1 / 19 (5.26%) 2
Pericardial effusion subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 1	1 / 19 (5.26%) 1
Palpitations subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 3	1 / 16 (6.25%) 1	0 / 19 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	0 / 16 (0.00%) 0	3 / 19 (15.79%) 4
Disturbance in attention			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	4 / 16 (25.00%)	1 / 16 (6.25%)	7 / 19 (36.84%)
occurrences (all)	5	1	7
Paraesthesia			
subjects affected / exposed	3 / 16 (18.75%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	3	0	2
Amnesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Asterixis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Aphasia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dizziness postural			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypogeusia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lethargy			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Neurotoxicity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Transient ischaemic attack			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	2 / 19 (10.53%)
occurrences (all)	0	3	3
Neutropenia			
subjects affected / exposed	2 / 16 (12.50%)	3 / 16 (18.75%)	3 / 19 (15.79%)
occurrences (all)	5	3	3
Leukocytosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	3
Febrile neutropenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Anaemia macrocytic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye disorders			
Cataract			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Visual impairment			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 1	0 / 19 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 16 (12.50%)	1 / 16 (6.25%)	3 / 19 (15.79%)
occurrences (all)	2	1	3
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	4 / 16 (25.00%)	2 / 16 (12.50%)	4 / 19 (21.05%)
occurrences (all)	4	2	6
Diarrhoea			
subjects affected / exposed	9 / 16 (56.25%)	6 / 16 (37.50%)	6 / 19 (31.58%)
occurrences (all)	17	8	11
Dyspepsia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Gastrointestinal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	7 / 16 (43.75%)	6 / 16 (37.50%)	11 / 19 (57.89%)
occurrences (all)	8	8	13
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	4 / 19 (21.05%)
occurrences (all)	1	0	4
Stomatitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	3 / 16 (18.75%)	2 / 16 (12.50%)	7 / 19 (36.84%)
occurrences (all)	5	2	12
Abdominal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2

Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Abdominal pain lower			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Swollen tongue			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Odynophagia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Oesophagitis subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Oral pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Tongue ulceration subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Hepatobiliary disorders Hypertransaminaemia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Jaundice subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	5 / 16 (31.25%) 5	3 / 16 (18.75%) 3	5 / 19 (26.32%) 5
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	2 / 19 (10.53%) 3
Pruritus subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 3	1 / 16 (6.25%) 1	2 / 19 (10.53%) 2
Dermatitis acneiform			

subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Erythema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Erythema multiforme			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Skin maceration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Skin hyperpigmentation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Skin ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Nephrolithiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Endocrine disorders			

Androgen deficiency subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Adrenal insufficiency subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Hyperprolactinaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	3 / 16 (18.75%) 3	3 / 16 (18.75%) 3	3 / 19 (15.79%) 4
Back pain subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 16 (6.25%) 1	1 / 19 (5.26%) 2
Muscular weakness subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 1	1 / 19 (5.26%) 1
Myalgia subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	3 / 16 (18.75%) 3	2 / 19 (10.53%) 2
Pain in extremity subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 16 (0.00%) 0	3 / 19 (15.79%) 3
Neck pain subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 16 (0.00%) 0	2 / 19 (10.53%) 2
Muscle spasms			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	2 / 16 (12.50%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Bursitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Soft tissue necrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Escherichia infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Lymphangitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Oral fungal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1

Tooth abscess subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Sputum purulent subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	1 / 19 (5.26%) 1
Metabolism and nutrition disorders			
Dehydration subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 2	2 / 19 (10.53%) 2
Decreased appetite subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	7 / 16 (43.75%) 7	5 / 19 (26.32%) 6
Hypercalcaemia subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	5 / 16 (31.25%) 6	1 / 16 (6.25%) 1	2 / 19 (10.53%) 2
Hypokalaemia subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	3 / 16 (18.75%) 6	5 / 19 (26.32%) 7
Hypomagnesaemia subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	4 / 16 (25.00%) 4	3 / 19 (15.79%) 5
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 16 (6.25%) 1	4 / 19 (21.05%) 4
Abnormal loss of weight subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 16 (0.00%) 0	0 / 19 (0.00%) 0
Cachexia			

subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Malnutrition			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 16 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 March 2020	<p>Added a weekly LV dosing schedule for all cohorts (tumor types) (Part B [q1wk dosing]). The existing dosing schedule for LV every 3 weeks is defined as Part A (q3wk dosing). Wording throughout the protocol was revised to reflect Part A and Part B as appropriate.</p> <p>Added clarifying language regarding timing of safety assessments. The assessment of safety during the course of this study will consist of the surveillance and recording of AEs including SAEs, recording of concomitant medication, and measurements of protocol-specified physical examination findings, vital signs, pregnancy testing, and laboratory tests. Safety assessments will be performed at prespecified time points through the EOT visit and in some circumstances beyond the EOT visit. AEs and SAEs will be reported through the EOT visit or 30 days after the last study treatment, whichever is later.</p>
27 August 2020	<p>Added tumor types: Cohort 7: castration-resistant prostate cancer and Cohort 8: melanoma. Wording throughout the protocol was revised to reflect the addition of Cohort 7 and Cohort 8 as appropriate. Added section "Safety data of LV q1wk".</p> <p>Added tumor assessment for prostate cancer participants. Updated rationale for selection of q1wk LV doses.</p>
12 October 2020	<p>Revised wording added: Withhold until toxicity resolves to \leq Grade 2 or baseline, then reduce dose to the next lower dose level if treatment is resumed. If the dose is held >48 hours, the dose may be omitted, and dosing may resume on the next scheduled dosing day. If Grade 4 neutropenia recurs, reduce dose to the next lower dose level if treatment is resumed, or discontinue at the discretion of the investigator.</p> <p>Revised wording added: The sponsor will report all SAEs, including SUSARs, to regulatory authorities as required per local legislation or regulatory reporting requirements.</p> <p>Revised wording added: Results of all clinical laboratory tests except pregnancy and PSA tests are to be submitted to iRIS.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported