



Clinical trial results:

An Open-Label, Multicenter, Phase II Study to Evaluate the Therapeutic Activity of Simlukafusp Alfa (RO6874281), an Immunocytokine, Consisting of Interleukin-2 Variant (IL-2v) Targeting Fibroblast Activation Protein- (FAP), in Combination with Atezolizumab (Anti-PD-L1), Administered Intravenously, in Participants with Advanced and/or Metastatic Solid Tumors

Summary

EudraCT number	2017-003182-94
Trial protocol	GB ES BE PL DE FR
Global end of trial date	30 December 2021

Results information

Result version number	v1 (current)
This version publication date	08 January 2023
First version publication date	08 January 2023

Trial information

Trial identification

Sponsor protocol code	BP40234
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03386721
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 +41 616878333, global.trial_information@roche.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	30 December 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 December 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the antitumor activity of simlukafusp alfa in combination with atezolizumab in participants with advanced and/or metastatic solid tumors. The main focus of this study was on participants with non-small cell lung cancer (NSCLC) and participants with squamous cell carcinoma (SCC) of the Head and Neck (HNSCC), esophagus (ESCC) and cervix (CSCC).

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 February 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 18
Country: Number of subjects enrolled	France: 29
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Israel: 9
Country: Number of subjects enrolled	Korea, Republic of: 19
Country: Number of subjects enrolled	New Zealand: 8
Country: Number of subjects enrolled	Poland: 19
Country: Number of subjects enrolled	Russian Federation: 4
Country: Number of subjects enrolled	Singapore: 7
Country: Number of subjects enrolled	Spain: 78
Country: Number of subjects enrolled	Switzerland: 2
Country: Number of subjects enrolled	Taiwan: 10
Country: Number of subjects enrolled	Turkey: 36
Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	United States: 2
Worldwide total number of subjects	256
EEA total number of subjects	145

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)	182
From 65 to 84 years	74
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 42 investigative sites in Belgium, France, Germany, Israel, Korea, New Zealand, Poland, Russia, Singapore, Spain, Switzerland, Taiwan, Turkey, United Kingdom, USA from 19 February 2018 to 30 December 2021.

Pre-assignment

Screening details:

A total of 256 participants were enrolled. 95 in NSCLC cohorts [Part I: A,B,D,F&Part II: E]; 161 in SCC cohorts (78 in HNSCC [Part III:G,H,K], 35 in ESCC [Part 3: I&M], & 48 in CSCC [Part III:J&N]) received simlukafusp alfa & atezolizumab. No participants were enrolled in Cohorts C&L as emerging data didn't lead to the need to open these cohorts.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	NSCLC: Part I Cohort A (QW/Q2W)

Arm description:

Checkpoint Inhibitor (CPI)-naïve participants with NSCLC, received simlukafusp alfa, 10 milligrams (mg), intravenous (IV) infusion, once weekly (QW) for the first 4 weeks, and every 2 weeks (Q2W) until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

Arm title	NSCLC: Part I Cohort B (QW/Q2W)
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Arm description:

CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

Arm type	Experimental
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Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

Arm title	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
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Arm description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

Arm title	NSCLC: Part I Cohort D, Arm 2 (Q3W)
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Arm description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion once in 3 weeks (Q3W) in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal

of consent, or for a maximum of 5.4 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

Arm title	NSCLC: Part I Cohort D, Arm 3 (Q3W)
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Arm description:

CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

Arm type	Active comparator
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Gemcitabine, IV infusion administered as per approved protocol.

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

Arm title	NSCLC: Part I Cohort F (Q3W)
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Arm description:

CPI-experienced, docetaxel naive participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:
Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

Arm title	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)
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Arm description:

NSCLC participants without prior treatment for metastatic disease and with high programmed death-ligand 1 (PD-L1) expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

Arm title	NSCLC: Part II Cohort E, Arm 2 (Q3W)
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Arm description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravenous use
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Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

Arm title	SCCHN: Part III Cohort G (Q3W)
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Arm description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

Arm title	SCCHN: Part III Cohort H (Q3W)
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Arm description:

CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

Arm title	ESCC: Part III Cohort I (Q3W)
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Arm description:

CPI-naïve participants with ESCC who were previously treated with standard therapy received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W

until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

Arm title	CSCC: Part III Cohort J (Q3W)
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Arm description:

CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

Arm type	Experimental
Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

Arm title	SCCHN: Part III Cohort K (QW/Q2W)
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Arm description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

Arm type	Experimental
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Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion, Solution for infusion
Routes of administration	Intravenous use, Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months

Arm title	ESCC: Part III Cohort M (QW/Q2W)
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Arm description:

Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion, Solution for infusion
Routes of administration	Intravenous use, Intravenous use

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months

Arm title	CSCC: Part III Cohort N (QW/Q2W)
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Arm description:

Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 840 mg, IV infusion, Q2W until disease progression, unacceptable toxicity, or withdrawal

of consent, or for a maximum of 0.68 months.

Investigational medicinal product name	Simlukafusp alfa
Investigational medicinal product code	RO6874281
Other name	FAP-IL2v active
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Simlukafusp alfa, 10 mg, IV infusion, QW for first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months

Number of subjects in period 1	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
Started	26	32	3
Completed	4	1	0
Not completed	22	31	3
Consent withdrawn by subject	1	2	-
Death	12	21	2
Progressive Disease	-	-	1
Site Terminated by Sponsor	5	5	-
Symptomatic Deterioration	-	-	-
Lost to follow-up	1	3	-
Reason not specified	3	-	-

Number of subjects in period 1	NSCLC: Part I Cohort D, Arm 2 (Q3W)	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)
Started	5	2	22
Completed	0	0	1
Not completed	5	2	21
Consent withdrawn by subject	-	-	-
Death	5	1	12
Progressive Disease	-	-	1
Site Terminated by Sponsor	-	1	3
Symptomatic Deterioration	-	-	-
Lost to follow-up	-	-	2
Reason not specified	-	-	3

Number of subjects in period 1	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)	SCCHN: Part III Cohort G (Q3W)
Started	3	2	23
Completed	0	0	1
Not completed	3	2	22
Consent withdrawn by subject	-	-	2
Death	1	1	12

Progressive Disease	-	-	2
Site Terminated by Sponsor	-	1	4
Symptomatic Deterioration	-	-	1
Lost to follow-up	1	-	1
Reason not specified	1	-	-

Number of subjects in period 1	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Started	30	33	47
Completed	0	2	6
Not completed	30	31	41
Consent withdrawn by subject	1	3	2
Death	20	21	21
Progressive Disease	1	1	-
Site Terminated by Sponsor	5	3	11
Symptomatic Deterioration	-	-	1
Lost to follow-up	2	1	-
Reason not specified	1	2	6

Number of subjects in period 1	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)
Started	25	2	1
Completed	0	0	0
Not completed	25	2	1
Consent withdrawn by subject	3	-	-
Death	14	2	1
Progressive Disease	1	-	-
Site Terminated by Sponsor	6	-	-
Symptomatic Deterioration	-	-	-
Lost to follow-up	-	-	-
Reason not specified	1	-	-

Baseline characteristics

Reporting groups

Reporting group title	NSCLC: Part I Cohort A (QW/Q2W)
Reporting group description: Checkpoint Inhibitor (CPI)-naïve participants with NSCLC, received simlukafusp alfa, 10 milligrams (mg), intravenous (IV) infusion, once weekly (QW) for the first 4 weeks, and every 2 weeks (Q2W) until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.	
Reporting group title	NSCLC: Part I Cohort B (QW/Q2W)
Reporting group description: CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.	
Reporting group title	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
Reporting group description: CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.	
Reporting group title	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Reporting group description: CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion once in 3 weeks (Q3W) in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.	
Reporting group title	NSCLC: Part I Cohort D, Arm 3 (Q3W)
Reporting group description: CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.	
Reporting group title	NSCLC: Part I Cohort F (Q3W)
Reporting group description: CPI-experienced, docetaxel naive participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.	
Reporting group title	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)
Reporting group description: NSCLC participants without prior treatment for metastatic disease and with high programmed death-ligand 1 (PD-L1) expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.	
Reporting group title	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Reporting group description: NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.	

Reporting group title	SCCHN: Part III Cohort G (Q3W)
Reporting group description: CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.	
Reporting group title	SCCHN: Part III Cohort H (Q3W)
Reporting group description: CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.	
Reporting group title	ESCC: Part III Cohort I (Q3W)
Reporting group description: CPI-naïve participants with ESCC who were previously treated with standard therapy received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.	
Reporting group title	CSCC: Part III Cohort J (Q3W)
Reporting group description: CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.	
Reporting group title	SCCHN: Part III Cohort K (QW/Q2W)
Reporting group description: CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.	
Reporting group title	ESCC: Part III Cohort M (QW/Q2W)
Reporting group description: Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.	
Reporting group title	CSCC: Part III Cohort N (QW/Q2W)
Reporting group description: Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.	

Reporting group values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
Number of subjects	26	32	3
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	58.0	59.8	63.7
standard deviation	± 10.5	± 9.9	± 3.8

Sex: Female, Male Units: participants			
Female	10	10	1
Male	16	22	2
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	23	28	3
Not Stated	1	2	0
Unknown	2	1	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	9	5	0
Native Hawaiian or Other Pacific Islander	2	0	0
Black or African American	0	1	0
White	15	26	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	NSCLC: Part I Cohort D, Arm 2 (Q3W)	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)
Number of subjects	5	2	22
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	65.6	63.5	57.4
standard deviation	± 4.3	± 4.9	± 8.9
Sex: Female, Male Units: participants			
Female	0	1	11
Male	5	1	11
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	4	2	20
Not Stated	1	0	1
Unknown	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	5
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	5	2	17
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)	SCCHN: Part III Cohort G (Q3W)
Number of subjects	3	2	23
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	56.7 ± 0.6	68.0 ± 2.8	55.7 ± 12.8
Sex: Female, Male Units: participants			
Female	1	0	5
Male	2	2	18
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	2	22
Not Stated	0	0	1
Unknown	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	3
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	0	0	0
White	2	2	19
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Number of subjects	30	33	47
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	58.8 ± 8.2	63.1 ± 9.6	51.3 ± 11.2
Sex: Female, Male Units: participants			
Female	7	10	47
Male	23	23	0
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	21	27	33
Not Stated	7	4	9
Unknown	1	2	5

Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	5	6	0
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	1	0	0
White	16	22	33
More than one race	0	0	0
Unknown or Not Reported	8	5	13

Reporting group values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)
Number of subjects	25	2	1
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	55.8	67.0	49.0
standard deviation	± 11.7	± 15.6	± 99999
Sex: Female, Male			
Units: participants			
Female	6	0	1
Male	19	2	0
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	23	1	1
Not Stated	2	1	0
Unknown	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	5	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	18	0	1
More than one race	0	0	0
Unknown or Not Reported	2	1	0

Reporting group values	Total		
Number of subjects	256		
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		

Sex: Female, Male Units: participants			
Female	110		
Male	146		
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	3		
Not Hispanic or Latino	213		
Not Stated	29		
Unknown	11		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	40		
Native Hawaiian or Other Pacific Islander	4		
Black or African American	2		
White	181		
More than one race	0		
Unknown or Not Reported	29		

End points

End points reporting groups

Reporting group title	NSCLC: Part I Cohort A (QW/Q2W)
Reporting group description: Checkpoint Inhibitor (CPI)-naïve participants with NSCLC, received simlukafusp alfa, 10 milligrams (mg), intravenous (IV) infusion, once weekly (QW) for the first 4 weeks, and every 2 weeks (Q2W) until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.	
Reporting group title	NSCLC: Part I Cohort B (QW/Q2W)
Reporting group description: CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.	
Reporting group title	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
Reporting group description: CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.	
Reporting group title	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Reporting group description: CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion once in 3 weeks (Q3W) in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.	
Reporting group title	NSCLC: Part I Cohort D, Arm 3 (Q3W)
Reporting group description: CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.	
Reporting group title	NSCLC: Part I Cohort F (Q3W)
Reporting group description: CPI-experienced, docetaxel naïve participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.	
Reporting group title	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)
Reporting group description: NSCLC participants without prior treatment for metastatic disease and with high programmed death-ligand 1 (PD-L1) expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.	
Reporting group title	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Reporting group description: NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.	

Reporting group title	SCCHN: Part III Cohort G (Q3W)
Reporting group description:	
CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.	
Reporting group title	SCCHN: Part III Cohort H (Q3W)
Reporting group description:	
CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.	
Reporting group title	ESCC: Part III Cohort I (Q3W)
Reporting group description:	
CPI-naïve participants with ESCC who were previously treated with standard therapy received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.	
Reporting group title	CSCC: Part III Cohort J (Q3W)
Reporting group description:	
CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.	
Reporting group title	SCCHN: Part III Cohort K (QW/Q2W)
Reporting group description:	
CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.	
Reporting group title	ESCC: Part III Cohort M (QW/Q2W)
Reporting group description:	
Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.	
Reporting group title	CSCC: Part III Cohort N (QW/Q2W)
Reporting group description:	
Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.	

Primary: Percentage of Participants with Objective Response Rate (ORR) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

End point title	Percentage of Participants with Objective Response Rate (ORR) According to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1 ^[1]
End point description:	
ORR was defined as the percentage of participants with observed tumor response of complete response (CR), or partial response (PR) determined according to RECIST version 1.1. CR was defined as the disappearance of all target lesions with reduction in target/non-target pathological lymph nodes to <10 millimeters (mm). PR was defined as at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. The percentages of participants are rounded off to the nearest single decimal point. Response evaluable population included all participants in the safety population who received at least one dose of simlukafusp alfa/atezolizumab and who had at least one baseline and one on-study tumor assessment.	
End point type	Primary

End point timeframe:

Baseline up to disease progression or study treatment discontinuation (up to 38 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: As pre specified in the protocol no formal statistical model and no formal hypothesis testing were planned in this for this endpoint.

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	32	3	5
Units: percentage of participants				
number (confidence interval 95%)	19.2 (8.51 to 37.88)	6.3 (1.73 to 20.15)	0 (0.00 to 56.15)	0 (0.00 to 43.45)

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[2]	21	3	2
Units: percentage of participants				
number (confidence interval 95%)	(to)	4.8 (0.85 to 22.67)	66.7 (20.77 to 93.85)	50.0 (9.45 to 90.55)

Notes:

[2] - Participants from this cohort were not included in the Response evaluable population.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	28	32	44
Units: percentage of participants				
number (confidence interval 95%)	18.2 (7.31 to 38.52)	3.6 (0.63 to 17.71)	21.9 (11.02 to 38.75)	27.3 (16.35 to 41.85)

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	2	1	
Units: percentage of participants				
number (confidence interval 95%)	4.0 (0.71 to 19.54)	0 (0.00 to 65.76)	0 (0.00 to 79.35)	

Statistical analyses

Secondary: Percentage of Participants with Disease Control Rate (DCR) Determined According to RECIST Version 1.1

End point title	Percentage of Participants with Disease Control Rate (DCR) Determined According to RECIST Version 1.1
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End point description:

DCR: percentage of participants with observed tumor response of CR, PR or stable disease (SD) as per RECIST v 1.1. CR: disappearance of all target lesions with reduction in target/non-target pathological lymph nodes to <10 mm. PR = at least a 30% decrease in the sum of diameters of target lesions, with reference to baseline sum diameters. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease (PD). PD = at least a 20% decrease in the sum of diameters of target lesions, with reference to smallest sum on study including baseline (nadir). The percentages of participants are rounded off to the nearest single decimal point. Response evaluable population = all participants in the safety population who received at least one dose of simlukafusp alfa/atezolizumab and who had at least one baseline and one on-study tumor assessment.

End point type	Secondary
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End point timeframe:

Baseline up to disease progression or study treatment discontinuation (up to 38 months)

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	32	3	5
Units: percentage of participants				
number (confidence interval 95%)	53.8 (35.46 to 71.24)	62.5 (45.25 to 77.07)	0 (0.00 to 56.15)	20.0 (3.62 to 62.45)

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[3]	21	3	2
Units: percentage of participants				
number (confidence interval 95%)	(to)	57.1 (36.55 to 75.53)	66.7 (20.77 to 93.85)	50.0 (9.45 to 90.55)

Notes:

[3] - Participants from this cohort were not included in the Response evaluable population

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	28	32	44
Units: percentage of participants				
number (confidence interval 95%)	50.0 (30.72 to 69.28)	14.3 (5.70 to 31.49)	43.8 (28.17 to 60.67)	68.2 (53.44 to 80.00)

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	2	1	
Units: percentage of participants				
number (confidence interval 95%)	36.0 (20.25 to 55.48)	50.0 (9.45 to 90.55)	0 (0.00 to 79.35)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR) According to RECIST Version 1.1

End point title	Duration of Response (DoR) According to RECIST Version 1.1
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End point description:

DoR was determined for participants who had a best overall response of CR or PR. CR = disappearance of all target lesions with reduction in target/non-target pathological lymph nodes to < 10 mm. PR = at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. DoR = time from first occurrence of a documented objective response until the time of documented disease progression or death from any cause during treatment, whichever occurs first. Participants that did not have documented progressive disease or death during the study were censored at the day of the last tumor assessment. Data could not be collected for this endpoint due to premature termination of the study by the sponsor.

End point type	Secondary
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End point timeframe:

From first occurrence of documented CR or PR up to disease progression or study treatment discontinuation (assessed every 8 weeks after study treatment start for the first year, and every 12 weeks thereafter, up to 38 months)

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[4]	0 ^[5]	0 ^[6]	0 ^[7]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[4] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[5] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[6] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[7] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[8]	0 ^[9]	0 ^[10]	0 ^[11]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[8] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[9] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[10] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[11] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[12]	0 ^[13]	0 ^[14]	0 ^[15]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[12] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[13] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[14] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[15] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[16]	0 ^[17]	0 ^[18]	
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[16] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[17] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

[18] - Data was not collected for this endpoint due to premature termination of the study by the sponsor.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) According to RECIST Version 1.1

End point title	Progression-Free Survival (PFS) According to RECIST Version 1.1
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End point description:

PFS was defined as the time from study treatment initiation (Cycle 1 Day 1 [1 cycle=14 days for QW/Q2W cohorts; 1 cycle=21 days for Q3W cohorts]) to the first occurrence of documented disease progression (based on Investigator's assessment) or death from any cause during treatment, whichever occurs first. Participants that did not have documented progressive disease or death during the study were censored at the day of the last tumor assessment. Here, 99999=Median and upper limit of 95% CI could not be calculated due to low number of participants with events. 0.99999=Lower limit of 95% CI could not be calculated as only one participant with events was evaluated. 999999=Upper limit of 95% CI could not be calculated as only one participant with events was evaluated. Response evaluable

population included all participants in the safety population who received at least one dose of simlukafusp alfa/atezolizumab and who had at least one baseline and one on-study tumor assessment.

End point type	Secondary
End point timeframe:	
Study treatment initiation up to disease progression or study treatment discontinuation (up to 38 months)	

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	32	3	5
Units: months				
median (confidence interval 95%)	3.5 (1.7 to 7.4)	3.7 (3.1 to 5.2)	2.0 (1.7 to 99999)	2.0 (1.9 to 99999)

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[19]	21	3	2
Units: months				
median (confidence interval 95%)	(to)	3.5 (1.9 to 5.5)	99999 (2.6 to 99999)	10.5 (1.9 to 99999)

Notes:

[19] - Participants from this cohort were not included in the Response evaluable population.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	28	32	44
Units: months				
median (confidence interval 95%)	2.5 (1.8 to 5.6)	1.9 (1.8 to 1.9)	1.9 (1.8 to 3.7)	3.7 (3.3 to 9.0)

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	2	1	
Units: months				
median (confidence interval 95%)	1.9 (1.6 to 3.2)	2.6 (1.6 to 99999)	1.9 (0.99999 to 999999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
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End point description:

OS was defined as the time from the first dose of study treatment to the time of death from any cause on study. Participants who were still alive at the time of analysis were censored at the last date known alive. As pre-specified in the protocol, data for OS was to be reported if data was mature at the time of analysis. The data was not reported for this endpoint as data was not matured and sufficient to be analysed during the analysis as the study was terminated prematurely and no safety follow for survival took place.

End point type	Secondary
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End point timeframe:

From first dose of study treatment up to death due to any cause (up to approximately 47 months)

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[20]	0 ^[21]	0 ^[22]	0 ^[23]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[20] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[21] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[22] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[23] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[24]	0 ^[25]	0 ^[26]	0 ^[27]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[24] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[25] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[26] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[27] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[28]	0 ^[29]	0 ^[30]	0 ^[31]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[28] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[29] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[30] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[31] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[32]	0 ^[33]	0 ^[34]	
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	

Notes:

[32] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[33] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

[34] - Data is not reported for this endpoint as data was not matured & sufficient to be analysed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Adverse Events (AEs)

End point title	Percentage of Participants with Adverse Events (AEs)
End point description:	
An AE is any untoward medical occurrence in a participant or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Safety Population included all participants who received at least one dose of study treatment, whether prematurely withdrawn from the study or not.	
End point type	Secondary
End point timeframe:	
Baseline up to end of the study (up to approximately 47 months)	

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	32	3	5
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	22	3	2
Units: percentage of participants				

number (not applicable)	100	100	100	100
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End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	30	33	47
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	25	2	1	
Units: percentage of participants				
number (not applicable)	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants by Programmed Death-Ligand 1 (PD-L1) Status According to Immunohistochemical Methods

End point title	Percentage of Participants by Programmed Death-Ligand 1 (PD-L1) Status According to Immunohistochemical Methods
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End point description:

Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to analyse PD-L1 impact.

End point type	Secondary
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End point timeframe:

Baseline

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[35]	0 ^[36]	0 ^[37]	0 ^[38]
Units: percentage of participants				

Notes:

[35] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[36] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[37] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[38] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[39]	0 ^[40]	0 ^[41]	0 ^[42]
Units: percentage of participants				

Notes:

[39] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[40] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[41] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[42] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[43]	0 ^[44]	0 ^[45]	0 ^[46]
Units: percentage of participants				

Notes:

[43] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[44] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[45] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[46] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[47]	0 ^[48]	0 ^[49]	
Units: percentage of participants				

Notes:

[47] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[48] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[49] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Density of Cluster of Differentiation (CD) 8 Positive (CD8+) Cells According to Immunohistochemical Methods

End point title	Change from Baseline in Density of Cluster of Differentiation (CD) 8 Positive (CD8+) Cells According to Immunohistochemical Methods
End point description: Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to be analysed during analysis.	
End point type	Secondary
End point timeframe: Baseline up to 2 months	

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[50]	0 ^[51]	0 ^[52]	0 ^[53]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[50] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[51] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[52] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[53] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[54]	0 ^[55]	0 ^[56]	0 ^[57]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[54] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[55] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[56] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[57] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[58]	0 ^[59]	0 ^[60]	0 ^[61]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[58] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[59] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[60] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[61] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[62]	0 ^[63]	0 ^[64]	
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[62] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[63] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[64] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Density of Cluster of Differentiation 3 Negative (CD3-) Perforin Positive Cells According to Immunohistochemical Methods

End point title	Change from Baseline in Density of Cluster of Differentiation 3 Negative (CD3-) Perforin Positive Cells According to Immunohistochemical Methods
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End point description:

Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to be analysed during analysis.

End point type	Secondary
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End point timeframe:

Baseline up to 2 months

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[65]	0 ^[66]	0 ^[67]	0 ^[68]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[65] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[66] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[67] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[68] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[69]	0 ^[70]	0 ^[71]	0 ^[72]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[69] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[70] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[71] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[72] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[73]	0 ^[74]	0 ^[75]	0 ^[76]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[73] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[74] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[75] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[76] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[77]	0 ^[78]	0 ^[79]	
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[77] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[78] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

[79] - Data was not reported as data was not matured and sufficient to be analysed during analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Density of PD-L1 According to Immunohistochemical Methods

End point title	Change from Baseline in Density of PD-L1 According to Immunohistochemical Methods
End point description:	Data was not collected for this endpoint post-baseline as baseline data was not matured and sufficient to analyse PD-L1 impact.
End point type	Secondary
End point timeframe:	Baseline up to 2 months

End point values	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)	NSCLC: Part I Cohort D, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[80]	0 ^[81]	0 ^[82]	0 ^[83]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[80] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[81] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[82] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[83] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

End point values	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[84]	0 ^[85]	0 ^[86]	0 ^[87]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[84] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[85] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[86] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[87] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

End point values	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)	ESCC: Part III Cohort I (Q3W)	CSCC: Part III Cohort J (Q3W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[88]	0 ^[89]	0 ^[90]	0 ^[91]
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[88] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[89] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[90] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[91] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

End point values	SCCHN: Part III Cohort K (QW/Q2W)	ESCC: Part III Cohort M (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[92]	0 ^[93]	0 ^[94]	
Units: Cell/mm (2)				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[92] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[93] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

[94] - Data was not reported as data was not matured and sufficient to analyse PD-L1 impact.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to end of the study (up to approximately 47 months)

Adverse event reporting additional description:

Safety-evaluable population included all participants who received at least one dose of study treatment, whether prematurely withdrawn from the study or not.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	NSCLC: Part I Cohort A (QW/Q2W)
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Reporting group description:

CPI-naïve participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 38 months.

Reporting group title	NSCLC: Part I Cohort B (QW/Q2W)
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Reporting group description:

CPI-experienced participants with NSCLC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 15.6 months.

Reporting group title	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
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Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 2.7 months.

Reporting group title	NSCLC: Part I Cohort D, Arm 2 (Q3W)
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Reporting group description:

CPI-experienced participants with NSCLC previously treated with platinum-containing regimen and docetaxel received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 5.4 months.

Reporting group title	NSCLC: Part I Cohort D, Arm 3 (Q3W)
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Reporting group description:

CPI-experienced participants with NSCLC who were previously treated with platinum-containing regimen and docetaxel received a gemcitabine, IV infusion as per approved protocol. Participants who had documented radiographic disease progression during or after treatment with gemcitabine received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 1.3 months.

Reporting group title	NSCLC: Part I Cohort F (Q3W)
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Reporting group description:

CPI-experienced, docetaxel naive participants with NSCLC who experienced disease progression during or after treatment with a platinum-containing regimen received, simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 26 months.

Reporting group title	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)
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Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 31.3 months.

Reporting group title	NSCLC: Part II Cohort E, Arm 2 (Q3W)
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Reporting group description:

NSCLC participants without prior treatment for metastatic disease and with high PD-L1 expression levels, received simlukafusp alfa, 10 mg, IV infusion Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 18.6 months.

Reporting group title	CSCC: Part III Cohort J (Q3W)
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Reporting group description:

CPI-naïve participants with CSCC who were previously treated with standard therapy, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 28.8 months.

Reporting group title	ESCC: Part III Cohort I (Q3W)
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Reporting group description:

CPI-naïve participants with ESCC who were previously treated with standard therapy received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 30.5 months.

Reporting group title	SCCHN: Part III Cohort G (Q3W)
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Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.6 months.

Reporting group title	SCCHN: Part III Cohort H (Q3W)
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Reporting group description:

CPI-experienced participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, Q3W in combination with atezolizumab, 1200 mg, IV infusion, Q3W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 10.3 months.

Reporting group title	ESCC: Part III Cohort M (QW/Q2W)
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Reporting group description:

Participants with ESCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 4.1 months.

Reporting group title	SCCHN: Part III Cohort K (QW/Q2W)
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Reporting group description:

CPI-naïve participants with SCCHN, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 24.3 months.

Reporting group title	CSCC: Part III Cohort N (QW/Q2W)
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Reporting group description:

Participants with CSCC, received simlukafusp alfa, 10 mg, IV infusion, QW for the first 4 weeks, and Q2W until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months. Participants also received atezolizumab, 840 mg, IV infusion, Q2W in combination with simlukafusp alfa until disease progression, unacceptable toxicity, or withdrawal of consent, or for a maximum of 0.68 months.

Serious adverse events	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 26 (50.00%)	25 / 32 (78.13%)	0 / 3 (0.00%)
number of deaths (all causes)	12	21	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (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
TUMOUR PAIN			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
Vascular disorders			
CAPILLARY LEAK SYNDROME			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EMBOLISM			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			

subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
MEDICAL DEVICE REMOVAL			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
FACIAL PAIN			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

INFLAMMATION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICAL DEVICE SITE HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (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
PERFORMANCE STATUS DECREASED			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
PYREXIA			

subjects affected / exposed	1 / 26 (3.85%)	4 / 32 (12.50%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
ANAPHYLACTIC SHOCK			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC IMMUNE ACTIVATION			
subjects affected / exposed	2 / 26 (7.69%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASPIRATION			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
ASTHMA			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOSPASM			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
COUGH			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (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
PHARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			

subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
PNEUMONITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OXYGEN SATURATION DECREASED			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
INCORRECT DOSE ADMINISTERED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 26 (0.00%)	3 / 32 (9.38%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	17 / 17	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICATION ERROR			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN LACERATION			

subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (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
UROSTOMY COMPLICATION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR ACCESS COMPLICATION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
TRACHEO-OESOPHAGEAL FISTULA			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

TACHYCARDIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
AGNOSIA			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
APHASIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEURALGIA			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYNEUROPATHY			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (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
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
DYSPHAGIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED ENTEROCOLITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH HAEMORRHAGE			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL FISTULA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL OBSTRUCTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL STENOSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS ACUTE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STENOSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DRUG-INDUCED LIVER INJURY			

subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
HEPATITIS			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
HEPATOTOXICITY			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
PRURITUS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEVENS-JOHNSON SYNDROME			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
HAEMATURIA			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHRITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELOCALIECTASIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
ADDISON'S DISEASE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED HYPOPHYSITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
BACTERAEMIA			

subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (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
BACTERIAL INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORNEAL INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA INFECTION			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH GLAND INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PELVIC INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONEAL ABSCESS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 26 (0.00%)	3 / 32 (9.38%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA NECROTISING			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY SEPSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPERCALCAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (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
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHOSPHATAEMIA			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALNUTRITION			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (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
TYPE 1 DIABETES MELLITUS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	NSCLC: Part I Cohort D, Arm 2 (Q3W)	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	2 / 2 (100.00%)	14 / 22 (63.64%)
number of deaths (all causes)	5	1	12
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
CAPILLARY LEAK SYNDROME			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EMBOLISM			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
MEDICAL DEVICE REMOVAL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FATIGUE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLAMMATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICAL DEVICE SITE HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERFORMANCE STATUS DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAPHYLACTIC SHOCK			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC IMMUNE ACTIVATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASPIRATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOSPASM			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

OROPHARYNGEAL PAIN	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHARYNGEAL HAEMORRHAGE	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY FAILURE	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders				
CONFUSIONAL STATE	subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues				

DEVICE DISLOCATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	1 / 1	0 / 0	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OXYGEN SATURATION DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
INCORRECT DOSE ADMINISTERED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	2 / 5 (40.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

MEDICATION ERROR			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN LACERATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSTOMY COMPLICATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR ACCESS COMPLICATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
TRACHEO-OESOPHAGEAL FISTULA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

MYOCARDITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TACHYCARDIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
AGNOSIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APHASIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEURALGIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYNEUROPATHY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 5 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED ENTEROCOLITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL FISTULA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL OBSTRUCTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL STENOSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS ACUTE			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	1 / 2 (50.00%)	0 / 22 (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
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STENOSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DRUG-INDUCED LIVER INJURY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOTOXICITY			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (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
Skin and subcutaneous tissue disorders			
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRURITUS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEVENS-JOHNSON SYNDROME			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHRITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELOCALIECTASIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

ADDISON'S DISEASE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED HYPOPHYSITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORNEAL INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH GLAND INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PELVIC INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONEAL ABSCESS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA NECROTISING			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY SEPSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN INFECTION			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPERCALCAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALNUTRITION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TYPE 1 DIABETES MELLITUS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)	CSCC: Part III Cohort J (Q3W)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	32 / 47 (68.09%)
number of deaths (all causes)	1	1	21
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
CAPILLARY LEAK SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EMBOLISM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
MEDICAL DEVICE REMOVAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
CHILLS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

MEDICAL DEVICE SITE HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERFORMANCE STATUS DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	5 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAPHYLACTIC SHOCK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

SYSTEMIC IMMUNE ACTIVATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASPIRATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOSPASM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OXYGEN SATURATION DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
INCORRECT DOSE ADMINISTERED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	7 / 47 (14.89%)
occurrences causally related to treatment / all	1 / 1	1 / 1	12 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICATION ERROR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 LACERATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSTOMY COMPLICATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 ACCESS COMPLICATION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
TRACHEO-OESOPHAGEAL FISTULA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TACHYCARDIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
AGNOSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

APHASIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEURALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYNEUROPATHY			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 47 (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
SYNCOPE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOCAL CORD PARALYSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED ENTEROCOLITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL FISTULA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 STENOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS ACUTE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STENOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DRUG-INDUCED LIVER INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOTOXICITY			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRURITUS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEVENS-JOHNSON SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
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 / 3 (0.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHRITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELOCALIECTASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
ADDISON'S DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED HYPOPHYSITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 47 (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

PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORNEAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH GLAND INFECTION			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PELVIC INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
PERITONEAL ABSCESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 47 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 NECROTISING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY SEPSIS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
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 INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR DEVICE INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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			
HYPERCALCAEMIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
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 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALNUTRITION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TYPE 1 DIABETES MELLITUS			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ESCC: Part III Cohort I (Q3W)	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 33 (60.61%)	15 / 23 (65.22%)	22 / 30 (73.33%)
number of deaths (all causes)	21	14	20
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
TUMOUR PAIN			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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			
CAPILLARY LEAK SYNDROME			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EMBOLISM			

subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
HYPOTENSION			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
MEDICAL DEVICE REMOVAL			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
General disorders and administration site conditions			
CHILLS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL PAIN			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
FATIGUE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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

GENERALISED OEDEMA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLAMMATION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICAL DEVICE SITE HAEMORRHAGE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
PERFORMANCE STATUS DECREASED			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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	1 / 33 (3.03%)	0 / 23 (0.00%)	3 / 30 (10.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAPHYLACTIC SHOCK			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC IMMUNE ACTIVATION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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			
ASPIRATION			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOSPASM			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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	2 / 33 (6.06%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOPTYSIS			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	0 / 30 (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
LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
PLEURAL EFFUSION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (3.03%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Psychiatric disorders			
CONFUSIONAL STATE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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			

ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCYTE COUNT DECREASED			

subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OXYGEN SATURATION DECREASED			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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			
INCORRECT DOSE ADMINISTERED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 33 (3.03%)	2 / 23 (8.70%)	3 / 30 (10.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICATION ERROR			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMORRHAGE			

subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
SKIN LACERATION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSTOMY COMPLICATION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 ACCESS COMPLICATION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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			
TRACHEO-OESOPHAGEAL FISTULA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

PERICARDIAL EFFUSION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TACHYCARDIA			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
Nervous system disorders			
AGNOSIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APHASIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
DIZZINESS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEURALGIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYNEUROPATHY			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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			
ANAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	3 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 UPPER			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
DYSPHAGIA			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
GASTRIC HAEMORRHAGE			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED ENTEROCOLITIS			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
OESOPHAGEAL OBSTRUCTION			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
OESOPHAGEAL STENOSIS			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
PANCREATITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS ACUTE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
VOMITING			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STENOSIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DRUG-INDUCED LIVER INJURY			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOTOXICITY			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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			
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRURITUS			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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
RASH			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
STEVENS-JOHNSON SYNDROME			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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	2 / 33 (6.06%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHRITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELOCALIECTASIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 FAILURE			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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			
ADDISON'S DISEASE			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
IMMUNE-MEDIATED HYPOPHYSITIS			

subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
Musculoskeletal and connective tissue disorders			
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
Infections and infestations			
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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

ASPERGILLUS INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL INFECTION			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
CORNEAL INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENCEPHALITIS			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
LYMPH GLAND INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PELVIC INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONEAL ABSCESS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	2 / 23 (8.70%)	2 / 30 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
PNEUMONIA BACTERIAL			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 NECROTISING			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 SEPSIS			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 DEVICE INFECTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
HYPERCALCAEMIA			
subjects affected / exposed	1 / 33 (3.03%)	2 / 23 (8.70%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
HYPOKALAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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 / 33 (0.00%)	2 / 23 (8.70%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALNUTRITION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TYPE 1 DIABETES MELLITUS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
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	ESCC: Part III Cohort M (QW/Q2W)	SCCHN: Part III Cohort K (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	14 / 25 (56.00%)	1 / 1 (100.00%)
number of deaths (all causes)	2	14	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MALIGNANT NEOPLASM PROGRESSION			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TUMOUR PAIN			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
CAPILLARY LEAK SYNDROME			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (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
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EMBOLISM			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULITIS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (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
Surgical and medical procedures			
MEDICAL DEVICE REMOVAL			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
CHILLS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FACIAL PAIN			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERALISED OEDEMA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLAMMATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICAL DEVICE SITE HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERFORMANCE STATUS DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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%)	1 / 25 (4.00%)	0 / 1 (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
Immune system disorders			
ANAPHYLACTIC REACTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAPHYLACTIC SHOCK			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC IMMUNE ACTIVATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

FEMALE GENITAL TRACT FISTULA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
ASPIRATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHMA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOSPASM			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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%)	1 / 25 (4.00%)	0 / 1 (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

LARYNGEAL HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

CONFUSIONAL STATE			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (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
Product issues			
DEVICE DISLOCATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 BILIRUBIN INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OXYGEN SATURATION DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			

INCORRECT DOSE ADMINISTERED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 2 (0.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	9 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MEDICATION ERROR			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 LACERATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSTOMY COMPLICATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR ACCESS COMPLICATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
TRACHEO-OESOPHAGEAL FISTULA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TACHYCARDIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
AGNOSIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APHASIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPILEPSY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEURALGIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POLYNEUROPATHY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

ANAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPENIA			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 UPPER			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC HAEMORRHAGE			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED ENTEROCOLITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MOUTH HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 STENOSIS			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS ACUTE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROCTALGIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (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
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STENOSIS			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DRUG-INDUCED LIVER INJURY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATOTOXICITY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRURITUS			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STEVENS-JOHNSON SYNDROME			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHRITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELOCALIECTASIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 FAILURE			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
ADDISON'S DISEASE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMMUNE-MEDIATED HYPOPHYSITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATHOLOGICAL FRACTURE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 ABDOMINAL WALL ABSCESS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
APPENDICITIS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
ARTHRITIS BACTERIAL subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
ASPERGILLUS INFECTION subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
BACTERAEemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	1 / 25 (4.00%) 0 / 1 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
BACTERIAL INFECTION subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
BRONCHITIS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
CELLULITIS subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0	0 / 25 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
CORNEAL INFECTION			

subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (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
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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%)	1 / 25 (4.00%)	0 / 1 (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
ENCEPHALITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPH GLAND INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PELVIC INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONEAL ABSCESS			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	1 / 2 (50.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA NECROTISING			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 SEPSIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 DEVICE INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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			
HYPERCALCAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (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
HYPERKALAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOALBUMINAEMIA			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
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 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALNUTRITION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TYPE 1 DIABETES MELLITUS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	NSCLC: Part I Cohort A (QW/Q2W)	NSCLC: Part I Cohort B (QW/Q2W)	NSCLC: Part I Cohort D, Arm 1 (QW/Q2W)
Total subjects affected by non-serious adverse events subjects affected / exposed	25 / 26 (96.15%)	32 / 32 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) TUMOUR PAIN subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 32 (3.13%) 1	0 / 3 (0.00%) 0
Vascular disorders CAPILLARY LEAK SYNDROME subjects affected / exposed occurrences (all) HOT FLUSH subjects affected / exposed occurrences (all) HYPERTENSION subjects affected / exposed occurrences (all) HYPOTENSION subjects affected / exposed occurrences (all) THROMBOSIS subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0 0 / 26 (0.00%) 0 1 / 26 (3.85%) 1 2 / 26 (7.69%) 2 0 / 26 (0.00%) 0	0 / 32 (0.00%) 0 0 / 32 (0.00%) 0 1 / 32 (3.13%) 1 11 / 32 (34.38%) 14 0 / 32 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0
General disorders and administration site conditions ASTHENIA subjects affected / exposed occurrences (all) CHEST PAIN subjects affected / exposed occurrences (all) CHILLS subjects affected / exposed occurrences (all) FATIGUE	6 / 26 (23.08%) 9 1 / 26 (3.85%) 1 12 / 26 (46.15%) 23	7 / 32 (21.88%) 8 1 / 32 (3.13%) 1 12 / 32 (37.50%) 23	2 / 3 (66.67%) 3 0 / 3 (0.00%) 0 1 / 3 (33.33%) 1

subjects affected / exposed	14 / 26 (53.85%)	15 / 32 (46.88%)	0 / 3 (0.00%)
occurrences (all)	25	21	0
HYPERTHERMIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
MALAISE			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
OEDEMA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
OEDEMA PERIPHERAL			
subjects affected / exposed	6 / 26 (23.08%)	4 / 32 (12.50%)	1 / 3 (33.33%)
occurrences (all)	6	7	1
PAIN			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
PYREXIA			
subjects affected / exposed	20 / 26 (76.92%)	29 / 32 (90.63%)	3 / 3 (100.00%)
occurrences (all)	197	91	11
XEROSIS			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Reproductive system and breast disorders			
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	4 / 26 (15.38%)	8 / 32 (25.00%)	2 / 3 (66.67%)
occurrences (all)	4	11	2
DYSPHONIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSPNOEA			
subjects affected / exposed	6 / 26 (23.08%)	7 / 32 (21.88%)	1 / 3 (33.33%)
occurrences (all)	8	10	1
HAEMOPTYSIS			
subjects affected / exposed	1 / 26 (3.85%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
NASAL CONGESTION			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	2 / 26 (7.69%)	3 / 32 (9.38%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
PNEUMONITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	3 / 26 (11.54%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	4	2	0
RHINORRHOEA			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			

subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
INSOMNIA			
subjects affected / exposed	4 / 26 (15.38%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	4	1	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	9 / 26 (34.62%)	9 / 32 (28.13%)	0 / 3 (0.00%)
occurrences (all)	24	12	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	12 / 26 (46.15%)	8 / 32 (25.00%)	0 / 3 (0.00%)
occurrences (all)	27	13	0
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	2 / 26 (7.69%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	4 / 26 (15.38%)	4 / 32 (12.50%)	0 / 3 (0.00%)
occurrences (all)	9	4	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	6 / 26 (23.08%)	6 / 32 (18.75%)	0 / 3 (0.00%)
occurrences (all)	15	11	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	3 / 26 (11.54%)	4 / 32 (12.50%)	0 / 3 (0.00%)
occurrences (all)	6	7	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
EOSINOPHIL COUNT INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	5 / 26 (19.23%)	4 / 32 (12.50%)	0 / 3 (0.00%)
occurrences (all)	5	9	0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
LIPASE INCREASED			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 26 (0.00%)	3 / 32 (9.38%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	8	6	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
PLATELET COUNT DECREASED			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
TRANSAMINASES INCREASED			
subjects affected / exposed	3 / 26 (11.54%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	8	0	0
WEIGHT DECREASED			
subjects affected / exposed	6 / 26 (23.08%)	0 / 32 (0.00%)	1 / 3 (33.33%)
occurrences (all)	7	0	1
WEIGHT INCREASED			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

WHITE BLOOD CELL COUNT DECREASED subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
Injury, poisoning and procedural complications INFUSION RELATED REACTION subjects affected / exposed occurrences (all) TOOTH FRACTURE subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 11 0 / 26 (0.00%) 0	7 / 32 (21.88%) 16 0 / 32 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0
Cardiac disorders CARDIAC FAILURE subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
Nervous system disorders DIZZINESS subjects affected / exposed occurrences (all) DYSGEUSIA subjects affected / exposed occurrences (all) HEADACHE subjects affected / exposed occurrences (all) HYPOAESTHESIA subjects affected / exposed occurrences (all) NEUROTOXICITY subjects affected / exposed occurrences (all) PRESYNCOPE subjects affected / exposed occurrences (all) SYNCOPE subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0 0 / 26 (0.00%) 0 4 / 26 (15.38%) 8 0 / 26 (0.00%) 0 0 / 26 (0.00%) 0 0 / 26 (0.00%) 0 0 / 26 (0.00%) 0	4 / 32 (12.50%) 4 2 / 32 (6.25%) 2 4 / 32 (12.50%) 6 0 / 32 (0.00%) 0 0 / 32 (0.00%) 0 1 / 32 (3.13%) 1 0 / 32 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 1 / 3 (33.33%) 1 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0

Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	3 / 26 (11.54%)	11 / 32 (34.38%)	0 / 3 (0.00%)
occurrences (all)	3	18	0
COAGULOPATHY			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTOSIS			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 26 (0.00%)	4 / 32 (12.50%)	0 / 3 (0.00%)
occurrences (all)	0	7	0
NEUTROPENIA			
subjects affected / exposed	3 / 26 (11.54%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	5	2	0
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 26 (3.85%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	2 / 26 (7.69%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 26 (3.85%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	5 / 26 (19.23%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	5	2	0
CONSTIPATION			

subjects affected / exposed	2 / 26 (7.69%)	3 / 32 (9.38%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
DIARRHOEA			
subjects affected / exposed	9 / 26 (34.62%)	9 / 32 (28.13%)	2 / 3 (66.67%)
occurrences (all)	17	10	2
DRY MOUTH			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
DYSPHAGIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
GASTROESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	1 / 26 (3.85%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
NAUSEA			
subjects affected / exposed	11 / 26 (42.31%)	10 / 32 (31.25%)	1 / 3 (33.33%)
occurrences (all)	22	11	2
ESOPHAGEAL PAIN			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
TOOTHACHE			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	10 / 26 (38.46%)	7 / 32 (21.88%)	1 / 3 (33.33%)
occurrences (all)	24	10	3
Hepatobiliary disorders			
HEPATOTOXICITY			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
DERMATITIS			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
DRY SKIN			
subjects affected / exposed	2 / 26 (7.69%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	4	2	0
ERYTHEMA			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	6 / 26 (23.08%)	6 / 32 (18.75%)	2 / 3 (66.67%)
occurrences (all)	11	8	2
RASH			
subjects affected / exposed	13 / 26 (50.00%)	5 / 32 (15.63%)	1 / 3 (33.33%)
occurrences (all)	26	5	1
RASH MACULAR			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	3 / 26 (11.54%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
RASH PRURITIC			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

URTICARIA subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 6	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
Renal and urinary disorders HAEMATURIA subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
PROTEINURIA subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
URINARY TRACT OBSTRUCTION subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
Endocrine disorders GLUCOCORTICOID DEFICIENCY subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
HYPERTHYROIDISM subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 4	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
HYPOTHYROIDISM subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 4	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all)	4 / 26 (15.38%) 4	5 / 32 (15.63%) 6	0 / 3 (0.00%) 0
ARTHRITIS subjects affected / exposed occurrences (all)	2 / 26 (7.69%) 2	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0
BACK PAIN subjects affected / exposed occurrences (all)	7 / 26 (26.92%) 8	2 / 32 (6.25%) 4	0 / 3 (0.00%) 0
BONE PAIN subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 32 (0.00%) 0	0 / 3 (0.00%) 0

MUSCLE SPASMS			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 26 (3.85%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
MYALGIA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
NECK PAIN			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
PAIN IN EXTREMITY			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Infections and infestations			
BACTERAEemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
CELLULITIS			
subjects affected / exposed	2 / 26 (7.69%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
GASTROENTERITIS			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			

subjects affected / exposed	1 / 26 (3.85%)	1 / 32 (3.13%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
PNEUMONIA			
subjects affected / exposed	1 / 26 (3.85%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 26 (0.00%)	3 / 32 (9.38%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
RHINITIS			
subjects affected / exposed	2 / 26 (7.69%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 26 (11.54%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	5	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 26 (3.85%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	7 / 26 (26.92%)	12 / 32 (37.50%)	2 / 3 (66.67%)
occurrences (all)	11	16	3
HYPERCALCAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
HYPERNATRAEMIA			

subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	1 / 26 (3.85%)	1 / 32 (3.13%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
HYPOALBUMINAEMIA			
subjects affected / exposed	2 / 26 (7.69%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	5	0	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	4 / 26 (15.38%)	0 / 32 (0.00%)	0 / 3 (0.00%)
occurrences (all)	9	0	0
HYPOMAGNESAEMIA			
subjects affected / exposed	3 / 26 (11.54%)	3 / 32 (9.38%)	0 / 3 (0.00%)
occurrences (all)	14	3	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 26 (0.00%)	2 / 32 (6.25%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	5 / 26 (19.23%)	4 / 32 (12.50%)	0 / 3 (0.00%)
occurrences (all)	12	15	0

Non-serious adverse events	NSCLC: Part I Cohort D, Arm 2 (Q3W)	NSCLC: Part I Cohort D, Arm 3 (Q3W)	NSCLC: Part I Cohort F (Q3W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	2 / 2 (100.00%)	21 / 22 (95.45%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
CAPILLARY LEAK SYNDROME			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
HOT FLUSH			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
HYPOTENSION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	6 / 22 (27.27%)
occurrences (all)	0	0	6
THROMBOSIS			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 5 (40.00%)	1 / 2 (50.00%)	7 / 22 (31.82%)
occurrences (all)	2	1	8
CHEST PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CHILLS			
subjects affected / exposed	2 / 5 (40.00%)	0 / 2 (0.00%)	9 / 22 (40.91%)
occurrences (all)	4	0	15
FATIGUE			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	6
HYPERTHERMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
MALAISE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			

subjects affected / exposed	0 / 5 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
OEDEMA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	5 / 5 (100.00%)	1 / 2 (50.00%)	15 / 22 (68.18%)
occurrences (all)	11	3	47
XEROSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 5 (0.00%)	1 / 2 (50.00%)	4 / 22 (18.18%)
occurrences (all)	0	1	4
DYSPHONIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DYSPNOEA			
subjects affected / exposed	0 / 5 (0.00%)	1 / 2 (50.00%)	3 / 22 (13.64%)
occurrences (all)	0	1	3
HAEMOPTYSIS			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
NASAL CONGESTION			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PNEUMONITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	1 / 5 (20.00%)	1 / 2 (50.00%)	3 / 22 (13.64%)
occurrences (all)	1	1	3
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	7
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	5 / 22 (22.73%)
occurrences (all)	1	0	9
BILIRUBIN CONJUGATED INCREASED			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
EOSINOPHIL COUNT INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			

subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
WEIGHT INCREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	2 / 5 (40.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	2	0	4
TOOTH FRACTURE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

CARDIAC FAILURE subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
Nervous system disorders			
DIZZINESS subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
DYSGEUSIA subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
HEADACHE subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 2 (50.00%) 2	0 / 22 (0.00%) 0
HYPOAESTHESIA subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
NEUROTOXICITY subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
PRESYNCOPE subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
SYNCOPE subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 2 (50.00%) 1	1 / 22 (4.55%) 1
Blood and lymphatic system disorders			
ANAEMIA subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 3	0 / 2 (0.00%) 0	5 / 22 (22.73%) 7
COAGULOPATHY subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
LEUKOPENIA subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	1 / 22 (4.55%) 1
LYMPHOCYTOSIS			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
NEUTROPENIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	3
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
CONSTIPATION			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
DIARRHOEA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	4
DRY MOUTH			
subjects affected / exposed	0 / 5 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
DYSPEPSIA			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
DYSPHAGIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	8 / 22 (36.36%)
occurrences (all)	0	0	11
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
TOOTHACHE			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
VOMITING			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	11 / 22 (50.00%)
occurrences (all)	1	0	16
Hepatobiliary disorders			
HEPATOTOXICITY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
DERMATITIS			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
DERMATITIS ACNEIFORM			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PRURITUS			
subjects affected / exposed	2 / 5 (40.00%)	0 / 2 (0.00%)	7 / 22 (31.82%)
occurrences (all)	2	0	8
RASH			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	3
RASH MACULAR			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
RASH PRURITIC			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
PROTEINURIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

URINARY TRACT OBSTRUCTION subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
Endocrine disorders			
GLUCOCORTICOID DEFICIENCY subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
HYPERTHYROIDISM subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
HYPOTHYROIDISM subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	1 / 22 (4.55%) 1
Musculoskeletal and connective tissue disorders			
ARTHRALGIA subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	1 / 22 (4.55%) 2
ARTHRITIS subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
BACK PAIN subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
BONE PAIN subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
MUSCLE SPASMS subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 2 (0.00%) 0	0 / 22 (0.00%) 0
MUSCULOSKELETAL CHEST PAIN subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	3 / 22 (13.64%) 3
MUSCULOSKELETAL PAIN subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 2 (0.00%) 0	1 / 22 (4.55%) 1
MYALGIA			

subjects affected / exposed	0 / 5 (0.00%)	1 / 2 (50.00%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
NECK PAIN			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Infections and infestations			
BACTERAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	5
CELLULITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
NASOPHARYNGITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1

RHINITIS			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 5 (40.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	1 / 5 (20.00%)	1 / 2 (50.00%)	6 / 22 (27.27%)
occurrences (all)	1	1	6
HYPERCALCAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
HYPERKALAEMIA			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
HYPERNATRAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	4
HYPOCALCAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			

subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 5 (0.00%)	0 / 2 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	1 / 5 (20.00%)	0 / 2 (0.00%)	2 / 22 (9.09%)
occurrences (all)	4	0	3

Non-serious adverse events	NSCLC: Part II Cohort E, Arm 1 (QW/Q2W)	NSCLC: Part II Cohort E, Arm 2 (Q3W)	CSCC: Part III Cohort J (Q3W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 2 (100.00%)	47 / 47 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
CAPILLARY LEAK SYNDROME			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
HYPERTENSION			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	1 / 47 (2.13%)
occurrences (all)	0	1	2
HYPOTENSION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	6 / 47 (12.77%)
occurrences (all)	0	0	8
THROMBOSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
General disorders and administration			

site conditions			
ASTHENIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	23 / 47 (48.94%)
occurrences (all)	2	0	28
CHEST PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
CHILLS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	12 / 47 (25.53%)
occurrences (all)	3	0	18
FATIGUE			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	9 / 47 (19.15%)
occurrences (all)	4	1	12
HYPERTHERMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences (all)	0	0	23
MALaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences (all)	0	0	5
OEDEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	7 / 47 (14.89%)
occurrences (all)	0	0	9
PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
PYREXIA			

subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 7	1 / 2 (50.00%) 3	35 / 47 (74.47%) 134
XEROSIS subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 47 (0.00%) 0
Reproductive system and breast disorders VAGINAL HAEMORRHAGE subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	3 / 47 (6.38%) 4
Respiratory, thoracic and mediastinal disorders CHRONIC OBSTRUCTIVE PULMONARY DISEASE subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	1 / 47 (2.13%) 7
COUGH subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	6 / 47 (12.77%) 6
DYSPHONIA subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	2 / 47 (4.26%) 2
DYSPNOEA subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	6 / 47 (12.77%) 8
HAEMOPTYSIS subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 47 (0.00%) 0
NASAL CONGESTION subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 47 (0.00%) 0
OROPHARYNGEAL PAIN subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	1 / 47 (2.13%) 1
PNEUMONITIS subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	0 / 47 (0.00%) 0
PRODUCTIVE COUGH			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	1	0	3
RHINORRHOEA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	5 / 47 (10.64%)
occurrences (all)	0	0	5
CONFUSIONAL STATE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	8 / 47 (17.02%)
occurrences (all)	0	0	9
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	21 / 47 (44.68%)
occurrences (all)	1	1	49
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	22 / 47 (46.81%)
occurrences (all)	1	1	56
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	3
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	11 / 47 (23.40%)
occurrences (all)	0	0	18
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	3 / 3 (100.00%)	0 / 2 (0.00%)	12 / 47 (25.53%)
occurrences (all)	10	0	14
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0

BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	6 / 47 (12.77%)
occurrences (all)	0	0	7
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	6 / 47 (12.77%)
occurrences (all)	3	0	8
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
EOSINOPHIL COUNT INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	3	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	16 / 47 (34.04%)
occurrences (all)	4	0	25
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences (all)	0	0	5
LIPASE INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	5 / 47 (10.64%)
occurrences (all)	0	0	9
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	5
PLATELET COUNT DECREASED			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	5 / 47 (10.64%)
occurrences (all)	1	0	7
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	3
WEIGHT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
WEIGHT INCREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	7 / 47 (14.89%)
occurrences (all)	1	0	16
TOOTH FRACTURE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
CARDIAC FAILURE			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	1	0	5
DYSGEUSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
HEADACHE			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	8 / 47 (17.02%)
occurrences (all)	3	0	9
HYPOAESTHESIA			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	3
NEUROTOXICITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	23 / 47 (48.94%)
occurrences (all)	0	0	40
COAGULOPATHY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	3
LEUKOPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	11
LYMPHOCYTOSIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	3	0	0
LYMPHOPENIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	6 / 47 (12.77%)
occurrences (all)	8	0	17
NEUTROPENIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	6 / 47 (12.77%)
occurrences (all)	0	0	12
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	6 / 47 (12.77%)
occurrences (all)	1	0	14
Ear and labyrinth disorders			
VERTIGO			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	10 / 47 (21.28%)
occurrences (all)	0	0	12
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
CONSTIPATION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	6 / 47 (12.77%)
occurrences (all)	0	0	9
DIARRHOEA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	17 / 47 (36.17%)
occurrences (all)	2	0	29
DRY MOUTH			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences (all)	0	0	4
DYSPEPSIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
DYSPHAGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
GASTROESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
NAUSEA			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	19 / 47 (40.43%)
occurrences (all)	2	0	46
OESOPHAGEAL PAIN			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
TOOTHACHE			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	18 / 47 (38.30%)
occurrences (all)	0	0	45
Hepatobiliary disorders			
HEPATOTOXICITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	5
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	1	0	8
Skin and subcutaneous tissue disorders			
DERMATITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	3
ERYTHEMA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	7
HYPERHIDROSIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	3
PRURITUS			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	8 / 47 (17.02%)
occurrences (all)	1	0	9
RASH			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	9 / 47 (19.15%)
occurrences (all)	6	0	15
RASH MACULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
RASH PRURITIC			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
URTICARIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	3
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences (all)	0	0	5
PROTEINURIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
GLUCOCORTICOID DEFICIENCY			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
HYPERTHYROIDISM			
subjects affected / exposed	3 / 3 (100.00%)	0 / 2 (0.00%)	4 / 47 (8.51%)
occurrences (all)	3	0	4
HYPOTHYROIDISM			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	3 / 47 (6.38%)
occurrences (all)	1	0	4
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	7 / 47 (14.89%)
occurrences (all)	0	1	9
ARTHRITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
BACK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	9 / 47 (19.15%)
occurrences (all)	0	0	10
BONE PAIN			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	1 / 47 (2.13%)
occurrences (all)	0	1	1
MUSCLE SPASMS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	2 / 47 (4.26%)
occurrences (all)	1	0	3
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
NECK PAIN			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	7 / 47 (14.89%)
occurrences (all)	0	0	7
Infections and infestations			

BACTERAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
BRONCHITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
CELLULITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
CONJUNCTIVITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
NASOPHARYNGITIS			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
PNEUMONIA			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	1	0	1
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 47 (0.00%)
occurrences (all)	0	2	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
URINARY TRACT INFECTION			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	14 / 47 (29.79%) 19
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	0 / 2 (0.00%) 0	12 / 47 (25.53%) 15
HYPERCALCAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	1 / 47 (2.13%) 1
HYPERGLYCAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 47 (0.00%) 0
HYPERKALAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	3 / 47 (6.38%) 3
HYPERNATRAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	0 / 47 (0.00%) 0
HYPERURICAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	1 / 47 (2.13%) 1
HYPOALBUMINAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	6 / 47 (12.77%) 10
HYPOCALCAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	4 / 47 (8.51%) 6
HYPOKALAEMIA			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0	9 / 47 (19.15%) 11
HYPOMAGNESAEMIA			
subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	0 / 2 (0.00%) 0	8 / 47 (17.02%) 13
HYPONATRAEMIA			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0	2 / 47 (4.26%) 4

HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	9 / 47 (19.15%)
occurrences (all)	0	0	9

Non-serious adverse events	ESCC: Part III Cohort I (Q3W)	SCCHN: Part III Cohort G (Q3W)	SCCHN: Part III Cohort H (Q3W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 33 (100.00%)	23 / 23 (100.00%)	29 / 30 (96.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
CAPILLARY LEAK SYNDROME			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
HOT FLUSH			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
HYPERTENSION			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
HYPOTENSION			
subjects affected / exposed	2 / 33 (6.06%)	4 / 23 (17.39%)	8 / 30 (26.67%)
occurrences (all)	3	5	11
THROMBOSIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	8 / 33 (24.24%)	9 / 23 (39.13%)	12 / 30 (40.00%)
occurrences (all)	8	10	12
CHEST PAIN			
subjects affected / exposed	3 / 33 (9.09%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	3	0	2
CHILLS			

subjects affected / exposed	12 / 33 (36.36%)	6 / 23 (26.09%)	10 / 30 (33.33%)
occurrences (all)	25	8	10
FATIGUE			
subjects affected / exposed	8 / 33 (24.24%)	6 / 23 (26.09%)	5 / 30 (16.67%)
occurrences (all)	11	9	6
HYPERTHERMIA			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	3
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
MALAISE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences (all)	0	3	2
OEDEMA			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences (all)	2	1	2
PAIN			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
subjects affected / exposed	26 / 33 (78.79%)	18 / 23 (78.26%)	22 / 30 (73.33%)
occurrences (all)	116	76	60
XEROSIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
VAGINAL HAEMORRHAGE			

subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	5	1	0
COUGH			
subjects affected / exposed	4 / 33 (12.12%)	2 / 23 (8.70%)	1 / 30 (3.33%)
occurrences (all)	5	2	1
DYSPHONIA			
subjects affected / exposed	0 / 33 (0.00%)	3 / 23 (13.04%)	0 / 30 (0.00%)
occurrences (all)	0	4	0
DYSPNOEA			
subjects affected / exposed	4 / 33 (12.12%)	2 / 23 (8.70%)	3 / 30 (10.00%)
occurrences (all)	5	2	3
HAEMOPTYSIS			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences (all)	0	1	4
NASAL CONGESTION			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
PNEUMONITIS			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	3 / 33 (9.09%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	3	1	1
RHINORRHOEA			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

ANXIETY			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
CONFUSIONAL STATE			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	4	0	0
INSOMNIA			
subjects affected / exposed	3 / 33 (9.09%)	3 / 23 (13.04%)	0 / 30 (0.00%)
occurrences (all)	5	3	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	14 / 33 (42.42%)	12 / 23 (52.17%)	6 / 30 (20.00%)
occurrences (all)	27	21	7
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	14 / 33 (42.42%)	16 / 23 (69.57%)	6 / 30 (20.00%)
occurrences (all)	25	37	9
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	5 / 33 (15.15%)	7 / 23 (30.43%)	4 / 30 (13.33%)
occurrences (all)	7	15	5
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	6 / 33 (18.18%)	5 / 23 (21.74%)	2 / 30 (6.67%)
occurrences (all)	7	10	4
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	1 / 33 (3.03%)	4 / 23 (17.39%)	1 / 30 (3.33%)
occurrences (all)	1	8	3
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	5	1	0

BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	3
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
EOSINOPHIL COUNT INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	5 / 33 (15.15%)	12 / 23 (52.17%)	9 / 30 (30.00%)
occurrences (all)	7	28	9
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
LIPASE INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	3 / 33 (9.09%)	3 / 23 (13.04%)	0 / 30 (0.00%)
occurrences (all)	9	10	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	3	0
PLATELET COUNT DECREASED			
subjects affected / exposed	2 / 33 (6.06%)	6 / 23 (26.09%)	2 / 30 (6.67%)
occurrences (all)	6	24	2
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
WEIGHT DECREASED			

subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2	2 / 23 (8.70%) 2	3 / 30 (10.00%) 3
WEIGHT INCREASED subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
WHITE BLOOD CELL COUNT DECREASED subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	4 / 23 (17.39%) 10	0 / 30 (0.00%) 0
Injury, poisoning and procedural complications INFUSION RELATED REACTION subjects affected / exposed occurrences (all)	5 / 33 (15.15%) 23	2 / 23 (8.70%) 13	1 / 30 (3.33%) 3
TOOTH FRACTURE subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
Cardiac disorders CARDIAC FAILURE subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
Nervous system disorders DIZZINESS subjects affected / exposed occurrences (all)	3 / 33 (9.09%) 3	1 / 23 (4.35%) 1	2 / 30 (6.67%) 2
DYSGEUSIA subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
HEADACHE subjects affected / exposed occurrences (all)	7 / 33 (21.21%) 13	2 / 23 (8.70%) 3	1 / 30 (3.33%) 1
HYPOAESTHESIA subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	2 / 23 (8.70%) 3	0 / 30 (0.00%) 0
NEUROTOXICITY subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
PRESYNCOPE			

subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	3 / 30 (10.00%)
occurrences (all)	1	0	3
SYNCOPE			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	7 / 33 (21.21%)	15 / 23 (65.22%)	9 / 30 (30.00%)
occurrences (all)	8	29	13
COAGULOPATHY			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	4
LEUKOPENIA			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	2	1	0
LYMPHOCYTOSIS			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
LYMPHOPENIA			
subjects affected / exposed	3 / 33 (9.09%)	4 / 23 (17.39%)	3 / 30 (10.00%)
occurrences (all)	17	15	7
NEUTROPENIA			
subjects affected / exposed	3 / 33 (9.09%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	4	0	1
THROMBOCYTOPENIA			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	4	1	1
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
ABDOMINAL PAIN			

subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
CONSTIPATION			
subjects affected / exposed	6 / 33 (18.18%)	5 / 23 (21.74%)	4 / 30 (13.33%)
occurrences (all)	7	6	5
DIARRHOEA			
subjects affected / exposed	7 / 33 (21.21%)	3 / 23 (13.04%)	5 / 30 (16.67%)
occurrences (all)	7	3	6
DRY MOUTH			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
DYSPEPSIA			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	2	12	0
DYSPHAGIA			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
NAUSEA			
subjects affected / exposed	13 / 33 (39.39%)	6 / 23 (26.09%)	7 / 30 (23.33%)
occurrences (all)	49	14	11
OESOPHAGEAL PAIN			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
STOMATITIS			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences (all)	0	1	2
TOOTHACHE			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0

VOMITING subjects affected / exposed occurrences (all)	3 / 33 (9.09%) 4	5 / 23 (21.74%) 19	5 / 30 (16.67%) 6
Hepatobiliary disorders HEPATOTOXICITY subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
HYPERBILIRUBINAEMIA subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 2	2 / 23 (8.70%) 3	0 / 30 (0.00%) 0
Skin and subcutaneous tissue disorders DERMATITIS subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
DERMATITIS ACNEIFORM subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
DRY SKIN subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	1 / 23 (4.35%) 2	1 / 30 (3.33%) 1
ERYTHEMA subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 3	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
HYPERHIDROSIS subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2	1 / 23 (4.35%) 1	2 / 30 (6.67%) 2
PRURITUS subjects affected / exposed occurrences (all)	4 / 33 (12.12%) 7	1 / 23 (4.35%) 1	2 / 30 (6.67%) 2
RASH subjects affected / exposed occurrences (all)	4 / 33 (12.12%) 7	7 / 23 (30.43%) 12	1 / 30 (3.33%) 1
RASH MACULAR subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	1 / 30 (3.33%) 4
RASH MACULO-PAPULAR			

subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
RASH PRURITIC subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
URTICARIA subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
Renal and urinary disorders HAEMATURIA subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 23 (4.35%) 1	0 / 30 (0.00%) 0
PROTEINURIA subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 23 (4.35%) 1	0 / 30 (0.00%) 0
URINARY TRACT OBSTRUCTION subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
Endocrine disorders GLUCOCORTICOID DEFICIENCY subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
HYPERTHYROIDISM subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	1 / 23 (4.35%) 1	0 / 30 (0.00%) 0
HYPOTHYROIDISM subjects affected / exposed occurrences (all)	7 / 33 (21.21%) 7	4 / 23 (17.39%) 4	1 / 30 (3.33%) 1
Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all)	5 / 33 (15.15%) 6	1 / 23 (4.35%) 1	2 / 30 (6.67%) 2
ARTHRITIS subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 23 (0.00%) 0	0 / 30 (0.00%) 0
BACK PAIN			

subjects affected / exposed	3 / 33 (9.09%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
BONE PAIN			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	4 / 33 (12.12%)	4 / 23 (17.39%)	0 / 30 (0.00%)
occurrences (all)	4	8	0
NECK PAIN			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Infections and infestations			
BACTERAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	2 / 23 (8.70%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
BRONCHITIS			
subjects affected / exposed	2 / 33 (6.06%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
CELLULITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	2
CONJUNCTIVITIS			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	1	2	0

GASTROENTERITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 33 (3.03%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
PNEUMONIA			
subjects affected / exposed	3 / 33 (9.09%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	3	0	1
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 33 (6.06%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	3	1	1
RHINITIS			
subjects affected / exposed	0 / 33 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 33 (6.06%)	3 / 23 (13.04%)	0 / 30 (0.00%)
occurrences (all)	2	3	0
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 33 (12.12%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	5	0	2
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	6 / 33 (18.18%)	4 / 23 (17.39%)	11 / 30 (36.67%)
occurrences (all)	8	5	11
HYPERCALCAEMIA			
subjects affected / exposed	3 / 33 (9.09%)	5 / 23 (21.74%)	2 / 30 (6.67%)
occurrences (all)	3	8	4
HYPERGLYCAEMIA			
subjects affected / exposed	1 / 33 (3.03%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
HYPERKALAEMIA			

subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
HYPERNATRAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	2 / 23 (8.70%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
HYPERURICAEMIA			
subjects affected / exposed	1 / 33 (3.03%)	3 / 23 (13.04%)	0 / 30 (0.00%)
occurrences (all)	1	4	0
HYPOALBUMINAEMIA			
subjects affected / exposed	1 / 33 (3.03%)	5 / 23 (21.74%)	2 / 30 (6.67%)
occurrences (all)	5	9	2
HYPOCALCAEMIA			
subjects affected / exposed	0 / 33 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
HYPOKALAEMIA			
subjects affected / exposed	2 / 33 (6.06%)	2 / 23 (8.70%)	3 / 30 (10.00%)
occurrences (all)	2	2	5
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 33 (6.06%)	4 / 23 (17.39%)	4 / 30 (13.33%)
occurrences (all)	3	5	6
HYPONATRAEMIA			
subjects affected / exposed	2 / 33 (6.06%)	8 / 23 (34.78%)	2 / 30 (6.67%)
occurrences (all)	4	13	2
HYPOPHOSPHATAEMIA			
subjects affected / exposed	4 / 33 (12.12%)	5 / 23 (21.74%)	5 / 30 (16.67%)
occurrences (all)	13	11	8

Non-serious adverse events	ESCC: Part III Cohort M (QW/Q2W)	SCCHN: Part III Cohort K (QW/Q2W)	CSCC: Part III Cohort N (QW/Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	24 / 25 (96.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
TUMOUR PAIN			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Vascular disorders			

CAPILLARY LEAK SYNDROME			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
HOT FLUSH			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	1 / 2 (50.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	1	4	0
HYPOTENSION			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
THROMBOSIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 2 (0.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
CHEST PAIN			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
CHILLS			
subjects affected / exposed	2 / 2 (100.00%)	9 / 25 (36.00%)	1 / 1 (100.00%)
occurrences (all)	7	49	3
FATIGUE			
subjects affected / exposed	0 / 2 (0.00%)	11 / 25 (44.00%)	1 / 1 (100.00%)
occurrences (all)	0	19	1
HYPERTHERMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
MALaise			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
MUCOSAL INFLAMMATION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
OEDEMA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
PAIN			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
subjects affected / exposed	2 / 2 (100.00%)	21 / 25 (84.00%)	1 / 1 (100.00%)
occurrences (all)	13	110	4
XEROSIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
COUGH			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
DYSPHONIA			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
DYSPNOEA			

subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
PNEUMONITIS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
INSOMNIA			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	9 / 25 (36.00%)	0 / 1 (0.00%)
occurrences (all)	0	13	0
ASPARTATE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	1 / 2 (50.00%)	11 / 25 (44.00%)	0 / 1 (0.00%)
occurrences (all)	1	21	0
BILIRUBIN CONJUGATED INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	8 / 25 (32.00%)	0 / 1 (0.00%)
occurrences (all)	0	15	0
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	6 / 25 (24.00%)	0 / 1 (0.00%)
occurrences (all)	0	6	0
BLOOD CHOLESTEROL INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
BLOOD CREATININE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
BLOOD LACTATE DEHYDROGENASE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	0	6	0
BLOOD URIC ACID INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
EOSINOPHIL COUNT INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	12 / 25 (48.00%)	0 / 1 (0.00%)
occurrences (all)	0	17	0
HEPATIC ENZYME INCREASED			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
LIPASE INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
LYMPHOCYTE COUNT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	16	0
NEUTROPHIL COUNT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
PLATELET COUNT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	0	8	0
TRANSAMINASES INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
WHITE BLOOD CELL COUNT DECREASED			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	9	0
Injury, poisoning and procedural complications			
INFUSION RELATED REACTION			
subjects affected / exposed	0 / 2 (0.00%)	5 / 25 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	24	0
TOOTH FRACTURE			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
Cardiac disorders CARDIAC FAILURE subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
Nervous system disorders DIZZINESS subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 25 (4.00%) 1	0 / 1 (0.00%) 0
DYSGEUSIA subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
HEADACHE subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	4 / 25 (16.00%) 10	1 / 1 (100.00%) 1
HYPOAESTHESIA subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
NEUROTOXICITY subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
PRESYNCOPE subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
SYNCOPE subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
Blood and lymphatic system disorders ANAEMIA subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	11 / 25 (44.00%) 29	0 / 1 (0.00%) 0
COAGULOPATHY subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 25 (0.00%) 0	0 / 1 (0.00%) 0
LEUKOPENIA			

subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
LYMPHOCYTOSIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
LYMPHOPENIA			
subjects affected / exposed	0 / 2 (0.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	0	25	0
NEUTROPENIA			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
CONSTIPATION			
subjects affected / exposed	2 / 2 (100.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
DIARRHOEA			
subjects affected / exposed	1 / 2 (50.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	2	4	0
DRY MOUTH			

subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
DYSPEPSIA			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
DYSPHAGIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	0 / 2 (0.00%)	11 / 25 (44.00%)	1 / 1 (100.00%)
occurrences (all)	0	44	1
OESOPHAGEAL PAIN			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
TOOTHACHE			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	1 / 1 (100.00%)
occurrences (all)	0	1	2
Hepatobiliary disorders			
HEPATOTOXICITY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
HYPERBILIRUBINAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Skin and subcutaneous tissue disorders			

DERMATITIS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
DRY SKIN			
subjects affected / exposed	1 / 2 (50.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
ERYTHEMA			
subjects affected / exposed	1 / 2 (50.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
HYPERHIDROSIS			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	7	0
PRURITUS			
subjects affected / exposed	1 / 2 (50.00%)	7 / 25 (28.00%)	0 / 1 (0.00%)
occurrences (all)	2	9	0
RASH			
subjects affected / exposed	1 / 2 (50.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	2	5	0
RASH MACULAR			
subjects affected / exposed	1 / 2 (50.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
RASH MACULO-PAPULAR			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
RASH PRURITIC			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
HAEMATURIA			

subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
PROTEINURIA			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	5	0
URINARY TRACT OBSTRUCTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Endocrine disorders			
GLUCOCORTICOID DEFICIENCY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
HYPERTHYROIDISM			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
HYPOTHYROIDISM			
subjects affected / exposed	0 / 2 (0.00%)	5 / 25 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	5	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	7	0
ARTHRITIS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	5	0
BACK PAIN			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
BONE PAIN			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
MUSCULOSKELETAL CHEST PAIN			

subjects affected / exposed	1 / 2 (50.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
NECK PAIN			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BACTERAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
CELLULITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
GASTROENTERITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0

PNEUMONIA			
subjects affected / exposed	1 / 2 (50.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 2 (0.00%)	3 / 25 (12.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
HYPERCALCAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
HYPERGLYCAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
HYPERKALAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
HYPERNATRAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	0 / 25 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
HYPOALBUMINAEMIA			

subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
HYPOCALCAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	1 / 25 (4.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
HYPOMAGNESAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	2 / 25 (8.00%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
HYPONATRAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	4 / 25 (16.00%)	0 / 1 (0.00%)
occurrences (all)	0	7	0
HYPOPHOSPHATAEMIA			
subjects affected / exposed	0 / 2 (0.00%)	5 / 25 (20.00%)	0 / 1 (0.00%)
occurrences (all)	0	7	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 May 2018	<p>1. Part I Cohort D was added to enroll platinum treatment experienced, CPI treatment experienced, docetaxel treatment experienced stage IV NSCLC participants. Cohort D comprised 3 arms. Arm 1 and Arm 2 explored different treatment schedules for RO6874281 in combination with atezolizumab. Participants in Arm 3 received gemcitabine or vinorelbine treatment and served as control.</p> <p>2. Part II Cohort E was added to enroll treatment naïve stage IV NSCLC participants that express high levels of PD-L1. Cohort E comprises 2 arms. Arm 1 and Arm 2 explored different treatment schedules for RO6874281 in combination with atezolizumab.</p>
23 August 2018	<p>1. An additional cohort, Cohort F, was added to Part I of this study. Forty response-evaluable participants were planned for this cohort in order to gain a better understanding of the safety and tolerability of the combination of RO6874281 and atezolizumab on a Q3W schedule in a specific NSCLC.</p> <p>2. An additional part, Part III, was added to the study design. Part III was dedicated to the exploration of RO6874281 in combination with atezolizumab in metastatic or locally advanced solid cancers with squamous histology. Part III comprised Cohorts G, H, I, and J.</p> <p>3. Implementation of a 10-mg flat dose based upon a simulation using the population pharmacokinetic model that showed overlapping exposures to the dosing regimens of 10 mg followed by 15 mg.</p>
29 March 2019	<p>1. An additional four cohorts (ie, Cohorts K, L, M, and N) were added to Part III of this study.</p> <p>2. The sample size of Cohorts D and E were changed due to early termination of these cohorts.</p> <p>3. Inclusion criteria were updated to align criteria across studies in the clinical development program and to clarify that the biopsy requirements enabling enrollment of participants with head and neck cancer presenting with one lesion does not apply to participants in Cohorts G, H, K, and L.</p> <p>4. The evaluation of preliminary activity based on immune-modified (im) RECIST was omitted.</p> <p>5. A general exclusion criterion (ie, exclusion #21) was added to indicate that a 28-day wash-out period from previous cytostatic treatment was required.</p> <p>6. Safety information pertaining to the risk associated with atezolizumab was updated by adding myositis as a new identified risk.</p> <p>7. The defined treatment lengths was updated.</p>
08 April 2019	The additional four cohorts (i.e., Cohorts K, M, and N and Cohort L) were added to the exclusion criteria.
16 December 2019	<p>Assessment of echocardiography was removed from the 28-day follow-up visit as the period between discontinuation and follow-up was not long enough to expect any clinically relevant changes in the outcome of repeated testing.</p> <p>2. Benefit risk was updated with new safety information. The enrollment into this study was suspended for participants that were naïve to checkpoint inhibitor treatment (CPI-naïve participants) that otherwise were eligible for CIT/CPI treatment as part of their 1L or 2L standard of care treatment for metastatic disease.</p> <p>3. Dose for QW/Q2W RO6874281 were added for Part III.</p>
25 June 2020	The main purpose of this amendment was to lift the temporary recruitment suspension for CPI-naïve participants that otherwise were eligible for CPI treatment as part of their 1L or 2L standard of care treatment and to resume enrollment for all CPI-naïve participants in study BP40234.

21 December 2020	<ol style="list-style-type: none"> 1. Severe cutaneous adverse reactions was added as a risk associated with atezolizumab. 2. Events suggestive of hemophagocytic lymphohistiocytosis or macrophage activation syndrome was added to the list of non-serious adverse events of special interest. 3. RO6874281 was replaced by simlukafusp alfa, the international nonproprietary name, throughout the protocol. 4. PD Sample (fluorescence-activated cell sorting [FACS]) Basic, PD Sample (Plasma), PD Sample (Serum) at 24, 36, 48, 60, 72, 84, and 96 weeks after Cycle 1 Day 1 and PD Sample (FACS) Advanced at 24, 48, and 96 weeks after Cycle 1 Day 1 were no longer collected in all cohorts irrespective of the treatment regimens, i.e., Q3W and QW/Q2W. 5. During the further conduct of the study, the collection of the on-treatment biopsy scheduled on Cycle 2 Day 8 and Cycle 3 Day 8 for the Q3W and the QW/Q2W schedule, respectively, were regarded as optional for participants enrolled in Part III. 5. A treatment cap of 24 months was added. However, in case the participant had reached the defined duration and continues to derive benefit, a longer treatment duration might be granted by the Sponsor.
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported