Clinical trial results:
An Open-Label, Multicenter, Dose Escalation and Expansion Phase Ib Study to Evaluate the Safety, Pharmacokinetics, and Therapeutic Activity of RO6958688 in Combination with Atezolizumab in Patients with Locally Advanced and/or Metastatic CEA-Positive Solid Tumors

Summary

EudraCT number	2015-003771-30
Trial protocol	
Global end of trial date	15 January 2020

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	WP29945

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02650713
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hoffmann-La Roche
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, 4070
Public contact	F. Hoffmann-La Roche AG, Hoffmann-La Roche, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, Hoffmann-La Roche, +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	15 January 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety, pharmacokinetics, and therapeutic activity of RO6958688 in combination with atezolizumab in patients with CEA-positive solid tumors, and to establish the appropriate dose and schedule of the combination treatment.

Protection of trial subjects:

All participants were required to sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 January 2016
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	Canada: 2
Country: Number of subjects enrolled	Denmark: 6
Country: Number of subjects enrolled	Spain: 122
Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Netherlands: 8
Country: Number of subjects enrolled	United States: 69
Worldwide total number of subjects	228
EEA total number of subjects	157

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)	169
From 65 to 84 years	59
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Locally advanced and/or metastatic CEA-positive solid tumors in participants who progressed on a standard therapy, were intolerant to standard of care, and/or were non-amenable to standard of care. Participants must also have had measurable disease according to RECIST v1.1.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg

Arm description:

Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received escalating doses starting from 5 mg up to 80 mg of RO6958688 on Days 1, 8, and 15 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg

Arm description:

Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 100 mg of RO6958688 on Days 1, 8, and 15 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Arm title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg

Arm description:

Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 160 mg of RO6958688 on Days 1, 8, and 15 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Arm title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg

Arm description:

Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 300 mg of RO6958688 on Days 1, 8, and 15 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Arm title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg

Arm description:

Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 100 mg of RO6958688 on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Arm title	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 1200 mg, then 1200 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 150 mg, then 150 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravenous use

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	Bile Duct

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	Breast

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Arm title	Lung

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	Pancreatic

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	Gastric

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Number of subjects in period 1	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Started	17	24	39
Completed	5	4	10
Not completed	12	20	29
Study Terminated by Sponsor	-	1	-
Disease Progression	1	1	2
Death	10	13	16
Physician decision	-	-	1
Symptomatic Deterioration	-	-	2
Not specified	1	1	3
Consent withdrawn by subject	-	4	5
Lost to follow-up	-	-	-

Number of subjects in period 1	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Started	1	20	17
Completed	1	4	4

Not completed	0	16	13
Study Terminated by Sponsor	-	-	-
Disease Progression	-	3	1
Death	-	10	12
Physician decision	-	-	-
Symptomatic Deterioration	-	1	-
Not specified	-	1	-
Consent withdrawn by subject	-	-	-
Lost to follow-up	-	1	-

Number of subjects in period 1	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg	Bile Duct
Started	39	35	2
Completed	16	10	0
Not completed	23	25	2
Study Terminated by Sponsor	-	1	-
Disease Progression	3	1	-
Death	15	18	2
Physician decision	-	1	-
Symptomatic Deterioration	-	-	-
Not specified	2	-	-
Consent withdrawn by subject	2	2	-
Lost to follow-up	1	2	-

Number of subjects in period 1	Breast	Lung	Pancreatic
Started	2	3	17
Completed	2	0	1
Not completed	0	3	16
Study Terminated by Sponsor	-	-	-
Disease Progression	-	1	2
Death	-	2	13
Physician decision	-	-	-
Symptomatic Deterioration	-	-	-
Not specified	-	-	1
Consent withdrawn by subject	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Gastric
Started	12
Completed	4
Not completed	8

Study Terminated by Sponsor	-
Disease Progression	2
Death	4
Physician decision	-
Symptomatic Deterioration	1
Not specified	-
Consent withdrawn by subject	1
Lost to follow-up	-

Reporting groups	
Reporting group title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).	
Reporting group title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Bile Duct
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Breast
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Lung
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Pancreatic
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Gastric

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Number of subjects	17	24	39
Age categorical Units: Subjects			
Adults (18-64 years)	15	18	28
From 65-84 years	2	6	11
Age Continuous			
9999 = not evaluable for one subject			
Units: years			
arithmetic mean	54.9	58.2	56.6
standard deviation	± 9.6	± 11.5	± 11.7
Sex: Female, Male Units: Participants			
Female	5	3	22
Male	12	21	17
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	2
White	17	24	36
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	5	3
Not Hispanic or Latino	14	19	36
Unknown or Not Reported	0	0	0

Reporting group values	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Number of subjects	1	20	17
Age categorical Units: Subjects			
Adults (18-64 years)	0	16	11
From 65-84 years	1	4	6
Age Continuous			
9999 = not evaluable for one subject			
Units: years			
arithmetic mean	75.0	56.5	59.4
standard deviation	± 9999	± 12.6	± 11.2

Sex: Female, Male Units: Participants			
Female	0	7	7
Male	1	13	10
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	1	19	17
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	5	0
Not Hispanic or Latino	1	14	17
Unknown or Not Reported	0	1	0

Reporting group values	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg	Bile Duct
Number of subjects	39	35	2
Age categorical Units: Subjects			
Adults (18-64 years)	29	28	0
From 65-84 years	10	7	2
Age Continuous			
9999 = not evaluable for one subject			
Units: years			
arithmetic mean	55.7	51.2	68.0
standard deviation	± 11.0	± 13.3	± 0.0
Sex: Female, Male Units: Participants			
Female	14	21	1
Male	25	14	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	1	0	0
White	38	32	2
More than one race	0	0	0
Unknown or Not Reported	0	2	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	5	1
Not Hispanic or Latino	37	29	1
Unknown or Not Reported	0	1	0

Reporting group values	Breast	Lung	Pancreatic
Number of subjects	2	3	17
Age categorical Units: Subjects			
Adults (18-64 years)	2	2	12
From 65-84 years	0	1	5
Age Continuous			
9999 = not evaluable for one subject			
Units: years arithmetic mean standard deviation	 49.0 ± 4.2	 62.7 ± 10.5	 59.5 ± 10.1
Sex: Female, Male Units: Participants			
Female	2	1	10
Male	0	2	7
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	3	15
More than one race	0	0	0
Unknown or Not Reported	0	0	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	3
Not Hispanic or Latino	2	2	11
Unknown or Not Reported	0	0	3

Reporting group values	Gastric	Total	
Number of subjects	12	228	
Age categorical Units: Subjects			
Adults (18-64 years)	8	169	
From 65-84 years	4	59	
Age Continuous			
9999 = not evaluable for one subject			
Units: years arithmetic mean standard deviation	 59.6 ± 13.5	 -	
Sex: Female, Male Units: Participants			
Female	3	96	
Male	9	132	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	2	

Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	0	3	
White	12	218	
More than one race	0	0	
Unknown or Not Reported	0	4	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	33	
Not Hispanic or Latino	6	189	
Unknown or Not Reported	1	6	

End points reporting groups

Reporting group title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).	
Reporting group title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Bile Duct
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Breast
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Lung
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Pancreatic
Reporting group description:	
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	
Reporting group title	Gastric

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Subject analysis set title	All Participants
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received up to 1200 mg of IV RO6958688 in combination with 1200 mg of atezolizumab.

Subject analysis set title	All MAD CRC 100-160 mg QW + Q3W
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants with colorectal cancer (CRC) that received RO6958688 either QW or Q3W in combination with 1200 mg of atezolizumab.

Subject analysis set title	ADA-Negative Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included all participants treated with an initial RO6958688 dose of > 20 mg in combination with 1200 mg of atezolizumab Q3W that were ADA-negative at baseline.

Subject analysis set title	40 mg-QW Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants that received 40 mg of IV RO6958688 weekly.

Subject analysis set title	80 mg-QW Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants that received 80 mg of IV RO6958688 weekly.

Subject analysis set title	100 mg-QW Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants that received 100 mg of IV RO6958688 weekly.

Subject analysis set title	160 mg-QW Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants that received 160 mg of IV RO6958688 weekly.

Subject analysis set title	300 mg-QW Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants that received 300 mg of IV RO6958688 weekly.

Subject analysis set title	100 mg-Q3W Cohort
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants that received 100 mg of IV RO6958688 Q3W.

Subject analysis set title	Atezolizumab PK Population
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group included participants that received at least one dose of atezolizumab and had at least one quantifiable concentration.

Primary: Number of Participants with Adverse Events (AEs)

End point title	Number of Participants with Adverse Events (AEs)[1]

End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical

product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events.

End point type	Primary

End point timeframe:

Baseline up to 60 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: No statistical analyses were planned for this phase I study.

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants	17	24	39	1

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants	20	17	39	35

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants	2	2	3	17

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of Participants	12			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Dose-Limiting Toxicities (DLTs)

End point title	Percentage of Participants with Dose-Limiting Toxicities (DLTs)

	[2]

End point description:

DLTs are side effects of drugs or other treatment serious enough to prevent an increase in dosage or level of treatment.

End point type	Primary

End point timeframe:

Day 1 up to Day 21

Notes:

[2] - 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: No statistical analyses were planned for this phase I study.

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	228			
Units: Percentage of Participants				
number (not applicable)	6.6			

Statistical analyses

No statistical analyses for this end point

Primary: Maximum-Tolerated Dose (MTD) of RO6958688

End point title	Maximum-Tolerated Dose (MTD) of RO6958688[3]

End point description:

The MTD is the highest dose of a drug or treatment that does not cause unacceptable side effects.

End point type	Primary

End point timeframe:

Day 1 up to Day 21, or Day 1 up to Day 7 after each dose escalation for step-up cohorts

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses were planned for this phase I study.

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17[4]	24[5]	39[6]	1[7]
Units: Milligrams (mg)	9999	9999	9999	9999

Notes:

[4] - 9999 = MTD not reached

[5] - 9999 = MTD not reached

[6] - 9999 = MTD not reached

[7] - 9999 = MTD not reached

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab

	1200 mg	1200 mg	1200 mg	1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20[8]	17[9]	39[10]	35[11]
Units: Milligrams (mg)	9999	9999	9999	9999

Notes:

[8] - 9999 = MTD not reached

[9] - 9999 = MTD not reached

[10] - 9999 = MTD not reached

[11] - 9999 = MTD not reached

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[12]	2[13]	3[14]	17[15]
Units: Milligrams (mg)	9999	9999	9999	9999

Notes:

[12] - 9999 = MTD not reached

[13] - 9999 = MTD not reached

[14] - 9999 = MTD not reached

[15] - 9999 = MTD not reached

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12[16]			
Units: Milligrams (mg)	9999			

Notes:

[16] - 9999 = MTD not reached

Statistical analyses

No statistical analyses for this end point

Primary: Recommended Phase II Dose (RP2D) of RO6958688

End point title	Recommended Phase II Dose (RP2D) of RO6958688[17][18]

End point description:

End point type	Primary

End point timeframe:

Day 1 up to 60 months

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses were planned for this phase I study.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to the groups reported.

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Milligrams (mg)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetic (PK): Area Under the Concentration-Time Curve (AUC) of RO6958688

End point title	Pharmacokinetic (PK): Area Under the Concentration-Time Curve (AUC) of RO6958688

End point description:

End point type	Secondary

End point timeframe:

Baseline up to 60 months

End point values	40 mg-QW Cohort	80 mg-QW Cohort	100 mg-QW Cohort	160 mg-QW Cohort
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	117[19]	5[20]	26[21]	42[22]
Units: (ug x h)/mL				
median (full range (min-max))	455 (183 to 797)	701 (396 to 751)	771 (395 to 1616)	1361 (521 to 2523)

Notes:

[19] - Range values are the 5th (min) and 95th (max) percentiles.

[20] - Range values are the 5th (min) and 95th (max) percentiles.

[21] - Range values are the 5th (min) and 95th (max) percentiles.

[22] - Range values are the 5th (min) and 95th (max) percentiles.

End point values	300 mg-QW Cohort	100 mg-Q3W Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3[23]	20[24]		
Units: (ug x h)/mL				
median (full range (min-max))	2378 (1999 to 3643)	756 (266 to 2398)		

Notes:

[23] - Range values are the 5th (min) and 95th (max) percentiles.

[24] - Range values are the 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Volume of Distribution at Steady State (Vss) of RO6958688

End point title	PK: Volume of Distribution at Steady State (Vss) of RO6958688

End point description:

End point type	Secondary

End point timeframe:

Baseline up to 60 months

End point values	ADA-Negative Population			
Subject group type	Subject analysis set			
Number of subjects analysed	59[25]			
Units: Liters				
median (full range (min-max))	8.31 (4.57 to 23.77)			

Notes:

[25] - Range values are the 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Maximum Serum Concentration (Cmax) of RO6958688

End point title	PK: Maximum Serum Concentration (Cmax) of RO6958688

End point description:

End point type	Secondary

End point timeframe:

Baseline up to 60 months

End point values	40 mg-QW Cohort	80 mg-QW Cohort	100 mg-QW Cohort	160 mg-QW Cohort
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	117[26]	5[27]	26[28]	42[29]
Units: ug/mL				
median (full range (min-max))	12.06 (7.92 to 19.9)	18.51 (15.94 to 26.72)	26.72 (19.37 to 40.61)	39.27 (30.16 to 58.45)

Notes:

[26] - Range values are the 5th (min) and 95th (max) percentiles.

[27] - Range values are the 5th (min) and 95th (max) percentiles.

[28] - Range values are the 5th (min) and 95th (max) percentiles.

[29] - Range values are the 5th (min) and 95th (max) percentiles.

End point values	300 mg-QW Cohort	100 mg-Q3W Cohort		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3[30]	20[31]		

Units: ug/mL				
median (full range (min-max))	88.96 (70.02 to 102.95)	26.7 (13.77 to 47.89)		

Notes:

[30] - Range values are the 5th (min) and 95th (max) percentiles.

[31] - Range values are the 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Clearance (CL) of RO6958688

End point title	PK: Clearance (CL) of RO6958688

End point description:

End point type	Secondary

End point timeframe:

Baseline up to 60 months

End point values	ADA-Negative Population			
Subject group type	Subject analysis set			
Number of subjects analysed	59[32]			
Units: L/h				
median (full range (min-max))	0.048 (0.026 to 0.113)			

Notes:

[32] - Range values are the 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Secondary: PK: Cmax of Atezolizumab

End point title	PK: Cmax of Atezolizumab

End point description:

End point type	Secondary

End point timeframe:

Baseline up to 60 months

End point values	Atezolizumab PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	180			
Units: ug/mL				
median (full range (min-max))	352 (69.4 to 690)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response (Partial Response [PR] or Complete Response [CR] as Assessed Using Response Evaluation Criteria in Solid Tumors [RECIST])

End point title	Percentage of Participants with Objective Response (Partial Response [PR] or Complete Response [CR] as Assessed Using Response Evaluation Criteria in Solid Tumors [RECIST])

End point description:

End point type	Secondary

End point timeframe:

Screening; every 8 weeks after the start of treatment for the first year, then every 12 weeks thereafter until disease progression or treatment discontinuation

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
number (not applicable)	0	12.5	15.4	0

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants				
number (not applicable)	15.0	0	5.1	0

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
number (not applicable)	0	0	0	0

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of Participants				
number (not applicable)	8.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Disease Control (PR, CR, or Stable Disease [SD]) as Assessed Using RECIST

End point title	Percentage of Participants with Disease Control (PR, CR, or Stable Disease [SD]) as Assessed Using RECIST

End point description:

End point type	Secondary

End point timeframe:

Screening; every 8 weeks after the start of treatment for the first year, then every 12 weeks thereafter until disease progression or treatment discontinuation

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
number (not applicable)	35.3	50.0	53.8	100.0

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35

Units: Percentage of Participants				
number (not applicable)	50.0	47.1	28.2	37.1

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
number (not applicable)	50.0	50.0	33.3	23.5

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of Participants				
number (not applicable)	41.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Stable Disease (SD) as Assessed Using RECIST

End point title	Percentage of Participants with Stable Disease (SD) as Assessed Using RECIST

End point description:

End point type	Secondary

End point timeframe:

Screening; every 8 weeks after the start of treatment for the first year, then every 12 weeks thereafter until disease progression or treatment discontinuation

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
number (not applicable)	35.3	37.5	38.5	100.0

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants				
number (not applicable)	35.0	47.1	23.1	37.1

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
number (not applicable)	50.0	50.0	33.3	23.5

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of Participants				
number (not applicable)	33.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) as Assessed Using RECIST

End point title	Duration of Response (DOR) as Assessed Using RECIST[33]

End point description:

End point type	Secondary

End point timeframe:

From initial objective response (PR or CR to the first disease progression or death from any cause (up to 60 months)

Notes:

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

End point values	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	39	20	39
Units: Months				
median (confidence interval 95%)	4.9 (3.8 to 6.9)	7.4 (3.7 to 28.6)	27.7 (3.6 to 27.7)	11.8 (6.0 to 17.6)

End point values	Gastric	All MAD CRC 100-160 mg QW + Q3W		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	12[34]	83		
Units: Months				
median (confidence interval 95%)	20.3 (-9999 to 9999)	5.9 (3.8 to 27.7)		

Notes:

[34] - 9999 = CI was not evaluable

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) according to RECIST V1.1

End point title	Progression-Free Survival (PFS) according to RECIST V1.1

End point description:

End point type	Secondary

End point timeframe:

From first study treatment to the first occurrence of objective disease progression or death from any cause (up to 60 months)

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1[35]
Units: Months				
median (confidence interval 95%)	2.0 (1.6 to 7.0)	2.7 (1.9 to 3.7)	3.5 (1.9 to 3.7)	5.2 (0 to 9999)

Notes:

[35] - 9999 = No CI for single participant

End point values	RO6958688 MAD 100 mg	RO6958688 Step Up B1 to	RO6958688 Step Up C1 to	RO6958688 Step Up C2 to

	Q3W CRC + Atezolizumab 1200 mg	1200 mg CRC + Atezolizumab 1200 mg	150 mg CRC + Atezolizumab 1200 mg	600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Months				
median (confidence interval 95%)	3.5 (2.1 to 3.8)	2.3 (2.0 to 3.1)	1.9 (1.7 to 3.0)	2.0 (1.9 to 3.6)

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Months				
median (confidence interval 95%)	2.8 (1.9 to 3.7)	2.8 (1.6 to 3.9)	1.9 (0.6 to 3.9)	1.7 (1.0 to 2.6)

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Months				
median (confidence interval 95%)	2.4 (1.2 to 9.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

End point type	Secondary

End point timeframe:

From first study treatment to death from any cause (up to 60 months)

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1[36]
Units: Months				
median (confidence interval 95%)	8.9 (5.0 to 18.8)	12.4 (7.8 to 25.6)	11.2 (7.1 to 13.7)	5.2 (0 to 9999)

Notes:
[36] - 9999 = no CI for n=1

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39[37]	35
Units: Months				
median (confidence interval 95%)	8.6 (4.0 to 15.5)	10.4 (5.0 to 18.4)	11.1 (8.5 to 9999)	14.5 (7.7 to 18.4)

Notes:
[37] - 9999 = value not estimable

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2[38]	3	17
Units: Months				
median (confidence interval 95%)	5.9 (5.1 to 6.7)	9999 (9999 to 9999)	13.0 (0.7 to 28.2)	5.5 (2.7 to 8.5)

Notes:
[38] - 9999 = insufficient participants with events

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Months				
median (confidence interval 95%)	3.9 (2.3 to 21.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)

End point title	Best Overall Response (BOR)

End point description:

End point type	Secondary

End point timeframe:
Baseline up to 60 months

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
median (confidence interval 95%)				
Complete Response	0 (0.0 to 16.2)	0 (0.0 to 11.7)	2.6 (0.1 to 11.6)	0 (0.0 to 95.0)
Partial Response	0 (0.0 to 16.2)	12.5 (3.5 to 29.2)	12.8 (5.2 to 25.1)	0 (0.0 to 95.0)
Stable Disease	35.3 (16.6 to 58.0)	37.5 (21.2 to 56.3)	38.5 (25.4 to 52.9)	100.0 (5.0 to 100.0)

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants				
median (confidence interval 95%)				
Complete Response	0 (0.0 to 13.9)	0 (0.0 to 16.2)	0 (0.0 to 7.4)	0 (0.0 to 8.2)
Partial Response	15.0 (4.2 to 34.4)	0 (0.0 to 16.2)	5.1 (0.9 to 15.3)	0 (0.0 to 8.2)
Stable Disease	35.0 (17.7 to 55.8)	47.1 (26.0 to 68.9)	23.1 (12.6 to 36.8)	37.1 (23.6 to 52.4)

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
median (confidence interval 95%)				
Complete Response	0 (0.0 to 77.6)	0 (0.0 to 77.6)	0 (0.0 to 63.2)	0 (0.0 to 16.2)
Partial Response	0 (0.0 to 77.6)	0 (0.0 to 77.6)	0 (0.0 to 63.2)	0 (0.0 to 16.2)
Stable Disease	50.0 (2.5 to 97.5)	50.0 (2.5 to 97.5)	33.3 (1.7 to 86.5)	23.5 (8.5 to 46.1)

End point values	Gastric			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percentage of Participants				
median (confidence interval 95%)				
Complete Response	0 (0.0 to 22.1)			

Partial Response Stable Disease	8.3 (0.4 to 33.9) 33.3 (12.3 to 60.9)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 60 months

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).

Reporting group title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.

Reporting group title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.

Reporting group title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.

Reporting group title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.

Reporting group title	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	Bile Duct

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	Breast

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	Lung

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	Pancreatic

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	Gastric

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Serious adverse events	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 17 (35.29%)	17 / 24 (70.83%)	24 / 39 (61.54%)
number of deaths (all causes)	13	15	24
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocele			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour fistulisation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 flare			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 inflammation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Cytokine release syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (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
Chills			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (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	2 / 17 (11.76%)	2 / 24 (8.33%)	4 / 39 (10.26%)
occurrences causally related to	0 / 2	2 / 2	4 / 4

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Psychotic disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	2 / 17 (11.76%)	10 / 24 (41.67%)	10 / 39 (25.64%)
occurrences causally related to treatment / all	2 / 2	19 / 19	14 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (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 bilirubin increased			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Cardiac arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 node pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (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
Dysarthria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 17 (5.88%)	3 / 24 (12.50%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	1 / 1	3 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 4	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 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 retention			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Pruritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 maculo-papular			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Biliary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to	0 / 0	0 / 0	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 E			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 candida			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Total subjects affected by serious			

adverse events			
subjects affected / exposed	1 / 1 (100.00%)	14 / 20 (70.00%)	9 / 17 (52.94%)
number of deaths (all causes)	1	15	14
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (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
Hypovolaemic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Lymphocele			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 fistulisation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
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 disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chills			
subjects affected / exposed	1 / 1 (100.00%)	0 / 20 (0.00%)	0 / 17 (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
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Psychiatric disorders			
Psychotic disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	9 / 20 (45.00%)	5 / 17 (29.41%)
occurrences causally related to treatment / all	0 / 0	11 / 11	14 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	2 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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 bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (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
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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

Liver function test increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Left ventricular dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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

Organising pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 node pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (100.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 varices haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 perforation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 pain			

subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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 and subcutaneous tissue disorders			
Pruritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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			
Biliary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 E			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 candida			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
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 respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg	Bile Duct
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 39 (56.41%)	25 / 35 (71.43%)	1 / 2 (50.00%)
number of deaths (all causes)	20	20	2
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocele			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour fistulisation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour inflammation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (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
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 39 (5.13%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to	0 / 0	1 / 1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 39 (0.00%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Psychotic disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	18 / 39 (46.15%)	15 / 35 (42.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	21 / 21	19 / 19	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (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
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Left ventricular dysfunction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (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
Haemoptysis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (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
Enteritis			
subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (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
Gastric varices haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subileus			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Cholangitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (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
Urticaria			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (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
Back pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Biliary tract infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic candida			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary tract infection			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (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

Serious adverse events	Breast	Lung	Pancreatic
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	13 / 17 (76.47%)
number of deaths (all causes)	0	3	15
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (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
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocele			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peripheral ischaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 fistulisation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 flare			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (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
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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%)	1 / 3 (33.33%)	0 / 17 (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
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Psychotic disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 2 (50.00%)	0 / 3 (0.00%)	4 / 17 (23.53%)
occurrences causally related to treatment / all	1 / 1	0 / 0	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
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 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (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	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (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
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

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 / 3 (0.00%)	0 / 17 (0.00%)
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 perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
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%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to	0 / 0	0 / 0	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Pruritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Biliary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 E			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
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 candida			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	0 / 17 (0.00%)
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 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Serious adverse events	Gastric		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)		
number of deaths (all causes)	10		
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolism			

subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypovolaemic shock				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphocele				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Superior vena cava syndrome				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Malignant melanoma in situ				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour fistulisation				

subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour flare				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour inflammation				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour pain				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Cytokine release syndrome				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Malaise				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	3 / 12 (25.00%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Psychotic disorder				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Fall				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infusion related reaction				
subjects affected / exposed	2 / 12 (16.67%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Procedural pneumothorax				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urine output decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular dysfunction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Organising pneumonia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bicytopenia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular coagulation				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymph node pain				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	0 / 12 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial pressure increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric varices haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all			
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Pruritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Biliary tract infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis E			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Systemic candida			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 17 (100.00%)	24 / 24 (100.00%)	38 / 39 (97.44%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Hot flush			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	2 / 39 (5.13%)
occurrences (all)	0	6	3
Jugular vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)

occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Raynaud's phenomenon			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	6 / 17 (35.29%)	1 / 24 (4.17%)	10 / 39 (25.64%)
occurrences (all)	7	3	23
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	10 / 17 (58.82%)	4 / 24 (16.67%)	16 / 39 (41.03%)
occurrences (all)	13	4	30
Catheter site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)

occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	11 / 17 (64.71%)	8 / 24 (33.33%)	14 / 39 (35.90%)
occurrences (all)	19	17	29
Cyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 17 (29.41%)	13 / 24 (54.17%)	14 / 39 (35.90%)
occurrences (all)	8	18	80
Gait disturbance			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Gravitational oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	1	2	1
Malaise			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Mucosal dryness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	3
Non-cardiac chest pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)

occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	5 / 24 (20.83%)	7 / 39 (17.95%)
occurrences (all)	0	6	10
Pain			
subjects affected / exposed	2 / 17 (11.76%)	3 / 24 (12.50%)	3 / 39 (7.69%)
occurrences (all)	3	3	3
Pyrexia			
subjects affected / exposed	13 / 17 (76.47%)	16 / 24 (66.67%)	17 / 39 (43.59%)
occurrences (all)	31	25	38
Swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Bradyphrenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	1 / 17 (5.88%)	3 / 24 (12.50%)	2 / 39 (5.13%)
occurrences (all)	1	3	3
Mania			

subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Paranoia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Penile rash			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Incision site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Infusion related reaction			
subjects affected / exposed	6 / 17 (35.29%)	12 / 24 (50.00%)	30 / 39 (76.92%)
occurrences (all)	9	42	62
Joint injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Skin abrasion			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Alanine aminotransferase increased			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	4 / 39 (10.26%)
occurrences (all)	1	1	5
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 17 (23.53%)	2 / 24 (8.33%)	4 / 39 (10.26%)
occurrences (all)	6	4	5
Blood albumin decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Blood bilirubin increased			
subjects affected / exposed	2 / 17 (11.76%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 17 (11.76%)	4 / 24 (16.67%)	1 / 39 (2.56%)
occurrences (all)	3	9	1
Blood fibrinogen decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 17 (17.65%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	3	1	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	6	0
Platelet count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	7
Serum ferritin decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	3 / 17 (17.65%)	3 / 24 (12.50%)	1 / 39 (2.56%)
occurrences (all)	3	3	1
White blood cell count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Bradycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	3
Ventricular fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Catarrh			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	7 / 17 (41.18%)	3 / 24 (12.50%)	9 / 39 (23.08%)
occurrences (all)	11	4	12
Dysphonia			
subjects affected / exposed	0 / 17 (0.00%)	6 / 24 (25.00%)	7 / 39 (17.95%)
occurrences (all)	0	6	8
Dyspnoea			
subjects affected / exposed	4 / 17 (23.53%)	2 / 24 (8.33%)	2 / 39 (5.13%)
occurrences (all)	6	2	2
Epistaxis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Nasal congestion			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)	4	1	5
Oropharyngeal pain			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	3 / 39 (7.69%)
occurrences (all)	0	3	3
Pleural effusion			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)

occurrences (all)	1	0	1
Pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Sputum discoloured			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 17 (23.53%)	4 / 24 (16.67%)	14 / 39 (35.90%)
occurrences (all)	4	4	22
Lymphopenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Thrombocytopenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Thrombocytosis			

subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Dizziness			
subjects affected / exposed	1 / 17 (5.88%)	4 / 24 (16.67%)	3 / 39 (7.69%)
occurrences (all)	1	5	3
Dysaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	10
Dysarthria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 17 (11.76%)	13 / 24 (54.17%)	21 / 39 (53.85%)
occurrences (all)	2	14	23
Headache			
subjects affected / exposed	3 / 17 (17.65%)	6 / 24 (25.00%)	3 / 39 (7.69%)
occurrences (all)	4	8	4
Hemianopia homonymous			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Monoparesis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1

Psychomotor hyperactivity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	3
Paraesthesia			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	2 / 39 (5.13%)
occurrences (all)	0	7	5
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	3 / 39 (7.69%)
occurrences (all)	0	1	4
Eye pruritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Lacrimation increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	3 / 39 (7.69%)
occurrences (all)	0	2	3
Orbital myositis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)

occurrences (all)	0	0	2

Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	6 / 17 (35.29%)	5 / 24 (20.83%)	11 / 39 (28.21%)
occurrences (all)	8	14	12
Abdominal pain upper			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)	1	1	6
Abdominal tenderness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Atrophic glossitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	2 / 17 (11.76%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Constipation			
subjects affected / exposed	4 / 17 (23.53%)	3 / 24 (12.50%)	7 / 39 (17.95%)

occurrences (all)	4	6	7
Diarrhoea			
subjects affected / exposed	9 / 17 (52.94%)	14 / 24 (58.33%)	26 / 39 (66.67%)
occurrences (all)	37	25	53
Dry mouth			
subjects affected / exposed	2 / 17 (11.76%)	5 / 24 (20.83%)	8 / 39 (20.51%)
occurrences (all)	2	6	30
Dyspepsia			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	2 / 39 (5.13%)
occurrences (all)	1	4	3
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	3 / 39 (7.69%)
occurrences (all)	0	0	7
Gastritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Gastrointestinal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	5 / 17 (29.41%)	8 / 24 (33.33%)	12 / 39 (30.77%)

occurrences (all)	8	16	19
Odynophagia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Rectal haemorrhage			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)	5	2	7
Toothache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 17 (29.41%)	5 / 24 (20.83%)	15 / 39 (38.46%)
occurrences (all)	6	8	18
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Anuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	2 / 39 (5.13%)
occurrences (all)	0	1	3
Leukocyturia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Polyuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	2 / 17 (11.76%)	2 / 24 (8.33%)	11 / 39 (28.21%)
occurrences (all)	3	2	12
Erythema			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hair colour changes			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	0 / 39 (0.00%)
occurrences (all)	0	4	0
Hypohidrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Palmar-plantar erythrodysaesthaesia syndrome			
subjects affected / exposed	0 / 17 (0.00%)	7 / 24 (29.17%)	4 / 39 (10.26%)

occurrences (all)	0	10	4
Papule			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pruritis			
subjects affected / exposed	4 / 17 (23.53%)	5 / 24 (20.83%)	10 / 39 (25.64%)
occurrences (all)	6	5	11
Rash			
subjects affected / exposed	1 / 17 (5.88%)	5 / 24 (20.83%)	2 / 39 (5.13%)
occurrences (all)	1	6	3
Rash erythematous			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	6 / 39 (15.38%)
occurrences (all)	1	2	6
Rash pruritic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	2 / 17 (11.76%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	2	2	1
Skin lesion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	6 / 24 (25.00%)	15 / 39 (38.46%)
occurrences (all)	0	9	34

Arthritis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	4 / 39 (10.26%)
occurrences (all)	1	0	8
Back pain			
subjects affected / exposed	5 / 17 (29.41%)	6 / 24 (25.00%)	7 / 39 (17.95%)
occurrences (all)	5	8	10
Dactylitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Immune-mediated arthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	2 / 39 (5.13%)
occurrences (all)	1	2	2
Myalgia			
subjects affected / exposed	2 / 17 (11.76%)	3 / 24 (12.50%)	3 / 39 (7.69%)
occurrences (all)	2	4	3

Neck pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Spondylitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Hypothyroidism			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 17 (17.65%)	9 / 24 (37.50%)	14 / 39 (35.90%)
occurrences (all)	3	10	19
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Diabetes mellitus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	3	0	2
Hyperkalaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)

occurrences (all)	1	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	3 / 39 (7.69%)
occurrences (all)	0	2	3
Hypocalcaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Hypomagnasaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Polydipsia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitamin B6 deficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 17 (5.88%)	3 / 24 (12.50%)	1 / 39 (2.56%)
occurrences (all)	1	6	1
Hypophosphataemia			
subjects affected / exposed	1 / 17 (5.88%)	4 / 24 (16.67%)	0 / 39 (0.00%)

occurrences (all)	1	7	0

Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	4 / 39 (10.26%)
occurrences (all)	2	1	9
Influenza			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Lip infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Oral candidiasis			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	1	2	0
Oral herpes			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0

Pharyngitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Skin candida			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	3 / 39 (7.69%)
occurrences (all)	1	2	3
Urinary tract infection			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)	1	1	5
Varicella			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg

Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 1 (100.00%)	20 / 20 (100.00%)	17 / 17 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	2 / 17 (11.76%)
occurrences (all)	0	3	2
Jugular vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	1 / 1 (100.00%)	1 / 20 (5.00%)	2 / 17 (11.76%)
occurrences (all)	1	1	3
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 1 (100.00%)	3 / 20 (15.00%)	10 / 17 (58.82%)
occurrences (all)	1	4	13
Catheter site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 1 (100.00%)	7 / 20 (35.00%)	3 / 17 (17.65%)
occurrences (all)	1	10	4
Cyst			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	7 / 20 (35.00%)	4 / 17 (23.53%)
occurrences (all)	0	11	4
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0

Gravitational oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Mucosal dryness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 1 (100.00%)	16 / 20 (80.00%)	4 / 17 (23.53%)
occurrences (all)	2	22	4
Swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Bradyphrenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Mania			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Paranoia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Penile rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Prostatitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural			

complications			
Incision site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	11 / 20 (55.00%)	14 / 17 (82.35%)
occurrences (all)	0	17	41
Joint injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	4 / 20 (20.00%)	2 / 17 (11.76%)
occurrences (all)	0	6	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	5 / 20 (25.00%)	3 / 17 (17.65%)
occurrences (all)	0	10	3
Blood albumin decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Blood creatine phosphokinase			

increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Blood fibrinogen decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Serum ferritin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Angina pectoris			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Atrial flutter			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Ventricular fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	3 / 17 (17.65%)

occurrences (all)	0	3	4
Dysphonia			
subjects affected / exposed	1 / 1 (100.00%)	3 / 20 (15.00%)	3 / 17 (17.65%)
occurrences (all)	1	4	3
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	3 / 17 (17.65%)
occurrences (all)	0	4	3
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	4
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Upper-airway cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	6 / 20 (30.00%)	3 / 17 (17.65%)
occurrences (all)	0	8	5
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0

Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	7 / 20 (35.00%)	4 / 17 (23.53%)
occurrences (all)	0	8	8
Headache			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Hemianopia homonymous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hyperaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Monoparesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)

occurrences (all)	0	1	0
Eye pruritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Orbital myositis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Periorbital swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Retinal artery occlusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	4 / 20 (20.00%)	4 / 17 (23.53%)
occurrences (all)	0	5	5

Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Abdominal tenderness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Anal fissure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Atrophic glossitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	4 / 17 (23.53%)
occurrences (all)	0	3	4
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	14 / 20 (70.00%)	9 / 17 (52.94%)
occurrences (all)	2	24	16
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1

Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Glossitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	7 / 20 (35.00%)	2 / 17 (11.76%)
occurrences (all)	1	10	2
Odynophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0

Vomiting			
subjects affected / exposed	1 / 1 (100.00%)	7 / 20 (35.00%)	4 / 17 (23.53%)
occurrences (all)	1	9	4
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Leukocyturia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Polyuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Portal vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Hair colour changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypohidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthaesia syndrome			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Papule			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pruritis			
subjects affected / exposed	0 / 1 (0.00%)	7 / 20 (35.00%)	2 / 17 (11.76%)
occurrences (all)	0	8	3
Rash			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	4 / 17 (23.53%)
occurrences (all)	0	2	4
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	2 / 17 (11.76%)
occurrences (all)	0	2	4

Rash pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Skin exfoliation			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	6 / 17 (35.29%)
occurrences (all)	0	4	7
Skin lesion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 20 (20.00%)	0 / 17 (0.00%)
occurrences (all)	0	7	0
Arthritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	3
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Dactylitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Immune-mediated arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Joint swelling			

subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Muscle contracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	4 / 17 (23.53%)
occurrences (all)	0	0	5
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0

Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 1 (100.00%)	9 / 20 (45.00%)	9 / 17 (52.94%)
occurrences (all)	2	9	13
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)

occurrences (all)	0	2	4
Hypomagnasaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vitamin B12 deficiency			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vitamin B6 deficiency			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	8	2
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 1 (100.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	1	2	1
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lip infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Skin candida			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tooth abscess			

subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vascular device infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg	Bile Duct
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 39 (97.44%)	35 / 35 (100.00%)	2 / 2 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hot flush			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Hypotension			

subjects affected / exposed	3 / 39 (7.69%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	8 / 39 (20.51%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	19	7	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	8 / 39 (20.51%)	7 / 35 (20.00%)	1 / 2 (50.00%)
occurrences (all)	12	12	1
Catheter site pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	9 / 39 (23.08%)	11 / 35 (31.43%)	1 / 2 (50.00%)
occurrences (all)	13	14	1
Cyst			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	16 / 39 (41.03%)	18 / 35 (51.43%)	0 / 2 (0.00%)
occurrences (all)	30	27	0
Gait disturbance			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	5 / 39 (12.82%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	5	3	0
Malaise			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Non-cardiac chest pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	4 / 39 (10.26%)	3 / 35 (8.57%)	1 / 2 (50.00%)
occurrences (all)	4	3	1
Pain			
subjects affected / exposed	3 / 39 (7.69%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
Pyrexia			
subjects affected / exposed	16 / 39 (41.03%)	15 / 35 (42.86%)	1 / 2 (50.00%)
occurrences (all)	22	24	2
Swelling			
subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Bradyphrenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 39 (2.56%)	5 / 35 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Mania			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paranoia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Penile rash			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Incision site pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	26 / 39 (66.67%)	18 / 35 (51.43%)	1 / 2 (50.00%)
occurrences (all)	68	37	6
Joint injury			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	8 / 39 (20.51%)	7 / 35 (20.00%)	1 / 2 (50.00%)
occurrences (all)	12	8	1
Aspartate aminotransferase increased			
subjects affected / exposed	9 / 39 (23.08%)	9 / 35 (25.71%)	0 / 2 (0.00%)
occurrences (all)	15	10	0
Blood albumin decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	3 / 39 (7.69%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Platelet count decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Tachycardia			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Ventricular fibrillation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	12 / 39 (30.77%)	10 / 35 (28.57%)	0 / 2 (0.00%)
occurrences (all)	14	13	0
Dysphonia			
subjects affected / exposed	6 / 39 (15.38%)	5 / 35 (14.29%)	1 / 2 (50.00%)
occurrences (all)	8	6	1
Dyspnoea			
subjects affected / exposed	5 / 39 (12.82%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	5	5	0
Epistaxis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Nasal congestion			

subjects affected / exposed	5 / 39 (12.82%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	6	7	0
Oropharyngeal pain			
subjects affected / exposed	3 / 39 (7.69%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
Pleural effusion			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 39 (17.95%)	10 / 35 (28.57%)	1 / 2 (50.00%)
occurrences (all)	8	12	1

Lymphopenia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Thrombocytosis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	3 / 39 (7.69%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Dysaesthesia			
subjects affected / exposed	5 / 39 (12.82%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	5	4	0
Dysarthria			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	20 / 39 (51.28%)	9 / 35 (25.71%)	1 / 2 (50.00%)
occurrences (all)	27	12	1
Headache			
subjects affected / exposed	4 / 39 (10.26%)	5 / 35 (14.29%)	0 / 2 (0.00%)
occurrences (all)	6	5	0
Hemianopia homonymous			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Monoparesis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	6 / 39 (15.38%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	7	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Eye pruritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Orbital myositis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	8 / 39 (20.51%)	11 / 35 (31.43%)	0 / 2 (0.00%)
occurrences (all)	17	24	0
Abdominal pain upper			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrophic glossitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	5 / 39 (12.82%)	7 / 35 (20.00%)	1 / 2 (50.00%)
occurrences (all)	8	8	1
Diarrhoea			
subjects affected / exposed	24 / 39 (61.54%)	19 / 35 (54.29%)	0 / 2 (0.00%)
occurrences (all)	53	32	0
Dry mouth			
subjects affected / exposed	4 / 39 (10.26%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	4	4	0
Dyspepsia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Dysphagia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Haematochezia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	5	1	0
Nausea			
subjects affected / exposed	11 / 39 (28.21%)	11 / 35 (31.43%)	0 / 2 (0.00%)
occurrences (all)	13	17	0
Odynophagia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	4 / 39 (10.26%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	4	2	0
Toothache			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	9 / 39 (23.08%)	8 / 35 (22.86%)	1 / 2 (50.00%)
occurrences (all)	11	13	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Anuria			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Leukocyturia			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Polyuria			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	7 / 39 (17.95%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	7	5	0
Erythema			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hair colour changes			
subjects affected / exposed	3 / 39 (7.69%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Hyperhidrosis			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)

occurrences (all)	2	1	0
Hypohidrosis			
subjects affected / exposed	3 / 39 (7.69%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Palmar-plantar erythrodysaesthaesia syndrome			
subjects affected / exposed	13 / 39 (33.33%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	18	7	0
Papule			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritis			
subjects affected / exposed	9 / 39 (23.08%)	8 / 35 (22.86%)	0 / 2 (0.00%)
occurrences (all)	13	10	0
Rash			
subjects affected / exposed	1 / 39 (2.56%)	5 / 35 (14.29%)	1 / 2 (50.00%)
occurrences (all)	1	6	1
Rash erythematous			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	6 / 39 (15.38%)	7 / 35 (20.00%)	0 / 2 (0.00%)
occurrences (all)	6	10	0
Rash pruritic			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Skin lesion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	10 / 39 (25.64%)	13 / 35 (37.14%)	0 / 2 (0.00%)
occurrences (all)	22	23	0
Arthritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	3 / 39 (7.69%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	7	4	0
Dactylitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune-mediated arthritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Muscular weakness			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Musculoskeletal pain			
subjects affected / exposed	2 / 39 (5.13%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	4	4	0
Myalgia			
subjects affected / exposed	7 / 39 (17.95%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	10	6	0
Neck pain			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Pain in extremity			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Spondylitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	8 / 39 (20.51%)	9 / 35 (25.71%)	0 / 2 (0.00%)
occurrences (all)	16	12	0
Dehydration			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	1 / 2 (50.00%)
occurrences (all)	1	2	2
Hyperkalaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 39 (2.56%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Hypocalcaemia			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hypoglycaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	3 / 39 (7.69%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Hypomagnasaemia			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Polydipsia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin B6 deficiency			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	2 / 39 (5.13%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	8 / 39 (20.51%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	8	3	0
Influenza			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lip infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Oropharyngeal candidiasis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	2 / 39 (5.13%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
Varicella			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Breast	Lung	Pancreatic
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	17 / 17 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Haemangioma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Skin papilloma			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Tumour flare			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	4 / 17 (23.53%)
occurrences (all)	1	6	4
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	3 / 3 (100.00%)	3 / 17 (17.65%)
occurrences (all)	1	5	4
Catheter site pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Chills			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	2 / 17 (11.76%)
occurrences (all)	2	3	2
Cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	6 / 17 (35.29%)
occurrences (all)	1	1	7
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)
occurrences (all)	0	0	3
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	7 / 17 (41.18%)
occurrences (all)	2	12	8
Swelling			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Temperature regulation disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Bradyphrenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Mania			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Panic attack			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paranoia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Penile rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Incision site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	3 / 3 (100.00%)	7 / 17 (41.18%)
occurrences (all)	0	3	13
Joint injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Blood fibrinogen decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Serum ferritin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Ventricular fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)
occurrences (all)	1	0	5
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	2 / 17 (11.76%)
occurrences (all)	0	2	2
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Sputum discoloured			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	3 / 17 (17.65%)
occurrences (all)	1	1	3
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Thrombocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	1	0	3

Dysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	8 / 17 (47.06%)
occurrences (all)	0	2	8
Headache			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
occurrences (all)	1	4	3
Hemianopia homonymous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Monoparesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye pruritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Orbital myositis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	5 / 17 (29.41%)
occurrences (all)	0	0	6
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Abdominal tenderness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Atrophic glossitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	5 / 17 (29.41%)
occurrences (all)	0	1	6
Diarrhoea			
subjects affected / exposed	2 / 2 (100.00%)	2 / 3 (66.67%)	10 / 17 (58.82%)
occurrences (all)	3	4	12
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)
occurrences (all)	0	0	3
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	5 / 17 (29.41%)
occurrences (all)	1	3	7
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2

Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	7 / 17 (41.18%)
occurrences (all)	0	3	10
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Nephritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0

Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
occurrences (all)	1	1	2
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hair colour changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypohidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthaesia syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	4 / 17 (23.53%)
occurrences (all)	0	0	4
Papule			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Pruritis			
subjects affected / exposed	2 / 2 (100.00%)	0 / 3 (0.00%)	6 / 17 (35.29%)
occurrences (all)	3	0	7
Rash			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)

occurrences (all)	1	0	4
Rash erythematous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	4 / 17 (23.53%)
occurrences (all)	0	0	5
Rash pruritic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	4 / 17 (23.53%)
occurrences (all)	0	1	4
Skin lesion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Solar dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Arthritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
occurrences (all)	1	2	2
Dactylitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Flank pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Immune-mediated arthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Spondylitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	5 / 17 (29.41%)
occurrences (all)	1	3	5
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)

occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypomagnasaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitamin B6 deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			

subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	2 / 17 (11.76%)
occurrences (all)	0	3	2
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lip infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Varicella			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Gastric		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Flushing			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Hypertension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hypotension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Jugular vein thrombosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Orthostatic hypotension subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Raynaud's phenomenon subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Thrombophlebitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Skin papilloma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Tumour flare subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Tumour pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Immune system disorders			
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Seasonal allergy			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	6 / 12 (50.00%)		
occurrences (all)	11		
Catheter site pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	4		
Cyst			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gravitational oedema			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Mucosal dryness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Mucosal inflammation subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Non-cardiac chest pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Oedema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	8 / 12 (66.67%) 14		
Swelling subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Temperature regulation disorder subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Localised oedema subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Bradyphrenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Confusional state subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Mania			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Panic attack			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Paranoia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Penile rash			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Prostatitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Incision site pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	4		
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Blood albumin decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Blood bilirubin increased			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Blood fibrinogen decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Lymphocyte count decreased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Serum ferritin decreased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Atrial flutter			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Sinus tachycardia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ventricular fibrillation			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bronchospasm			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Catarrh			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	3		
Epistaxis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sputum discoloured			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Throat irritation			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Upper-airway cough			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		
Lymphopenia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Thrombocytosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	4 / 12 (33.33%)		
occurrences (all)	5		
Headache			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Hemianopia homonymous			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0		
Monoparesis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Psychomotor hyperactivity			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Eye pruritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Orbital myositis			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Periorbital swelling			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Retinal artery occlusion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0			
Atrophic glossitis				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	1			
Colitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	8 / 12 (66.67%)			
occurrences (all)	16			
Dry mouth				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Enteritis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastrointestinal pain				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Glossitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	0 / 12 (0.00%)			

occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	8 / 12 (66.67%)		
occurrences (all)	12		
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Salivary hypersecretion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	7 / 12 (58.33%)		
occurrences (all)	8		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Anuria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysuria			

subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nephritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Polyuria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Portal vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Hair colour changes			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0			
Hyperhidrosis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypohidrosis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Palmar-plantar erythrodysaesthaesia syndrome				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	3			
Papule				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Pruritis				
subjects affected / exposed	3 / 12 (25.00%)			
occurrences (all)	4			
Rash				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	3			
Rash erythematous				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Rash pruritic				
subjects affected / exposed	2 / 12 (16.67%)			
occurrences (all)	3			
Skin exfoliation				
subjects affected / exposed	2 / 12 (16.67%)			
occurrences (all)	2			
Skin lesion				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Solar dermatitis				

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	6		
Arthritis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Dactylitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Immune-mediated arthritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle contracture			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Musculoskeletal chest pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Myalgia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Neck pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Pain in extremity subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Spondylitis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Metabolism and nutrition disorders Cachexia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Decreased appetite subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2		
Dehydration subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Diabetes mellitus			

subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypercholesterolaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hyperglycaemia				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	1			
Hyperkalaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypertriglyceridaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypoalbuminaemia				
subjects affected / exposed	4 / 12 (33.33%)			
occurrences (all)	4			
Hypocalcaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypoglycaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypokalaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypomagnasaemia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Polydipsia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Vitamin B12 deficiency				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Vitamin B6 deficiency				

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lip infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	4		
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Oral herpes				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Oropharyngeal candidiasis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Skin candida				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Tooth abscess				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Urinary tract infection				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	1			
Varicella				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			

Vascular device infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 February 2016	Changes to eligibility criteria
11 May 2016	Changes to eligibility criteria
13 December 2016	Add new biomarker cohort
03 August 2017	Increased sample size; changes to eligibility criteria
14 April 2018	Add pretreatment cohorts; updates to eligibility criteria; increased sample size
24 September 2018	Updates to enrollment and eligibility criteria; remove obinutuzumab pretreatment
18 May 2019	Changes to secondary outcome measures

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The final study report was abbreviated due to early study termination due to non-safety reasons.

Notes: