Clinical trial results:
An Open-Label, Multicenter, Dose-Escalation Phase I Study to Evaluate the Safety, Pharmacokinetics, and Therapeutic Activity of Cibisatamab, a Novel T-Cell Bispecific Antibody that Targets the Human Carcinoembryonic Antigen (CEA) on Tumor Cells and CD3 on T Cells, Administered Intravenously in Patients with Locally Advanced and/or Metastatic CEA(+) Solid Tumors

Summary

EudraCT number	2014-003075-30
Trial protocol	
Global end of trial date	03 September 2019

Results information

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

Trial information

Trial identification

Sponsor protocol code	BP29541

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02324257
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	03 September 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This was a first-in-human study of single-agent cibisatamab (RO6958688) in participants with locally advanced and/or metastatic carcinoembryonic antigen (CEA) positive solid tumors who have progressed on standard treatment, are intolerant to standard of care (SOC), and/or are non-amenable to SOC.

Protection of trial subjects:

All participants were required to sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 December 2014
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: 1
Country: Number of subjects enrolled	Denmark: 6
Country: Number of subjects enrolled	Spain: 83
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Netherlands: 31
Country: Number of subjects enrolled	United States: 27
Worldwide total number of subjects	149
EEA total number of subjects	121

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)	100
From 65 to 84 years	49
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants with locally advanced and/or metastatic CEA-positive solid tumors who have progressed on standard treatment, are intolerant to SOC, and/or are non-amenable to SOC.

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	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)

Arm description:

Participants with colorectal cancer (CRC) received a single administration of up to 2.5 mg intravenous (IV) cibisatamab without OB pre-treatment

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

Dosage and administration details:

Participants received intravenous (IV) cibisatamab as a single administration up to a maximum dose of 2.5 mg.

Arm title	Cibisatamab MAD 5-60 mg QW CRC without OB

Arm description:

Participants with CRC received up to 60 mg of IV cibisatamab QW without OB pre-treatment.

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

Dosage and administration details:

Participants received IV cibisatamab QW.

Arm title	Cibisatamab MAD 90-200 mg QW CRC without OB

Arm description:

Participants with CRC received up to 200 mg of IV cibisatamab QW without OB pre-treatment.

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

Dosage and administration details:

Participants received IV cibisatamab QW.

Arm title	Cibisatamab MAD 300-600 mg QW CRC without OB

Arm description:

Participants with CRC received up to 600 mg of IV cibisatamab QW without OB pre-treatment.

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

Dosage and administration details:

Participants received IV cibisatamab QW.

Arm title	Cibisatamab Step Up A/B CRC without OB

Arm description:

Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 100% of the previous dose until the DLT criteria for that dose level was met (Cohort A). Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 150% of the previous dose up to 200 mg, and then QW by up to 100% until the DLT criteria for that dose was met (Cohort B).

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

Dosage and administration details:

Cohort A: Participants received a starting dose of 40 mg IV cibisatamab in Cycle 1, and escalated QW by up to 100% of the previous dose until the DLT criteria for that dose level was met.

Cohort B: Participants received a starting dose of 40 mg IV cibisatamab in Cycle 1 and escalated QW by up to 150% of the previous dose up to 200 mg, and then QW by up to 100% until the DLT criteria for that dose was met.

Arm title	Cibisatamab Step Up C CRC without OB

Arm description:

Participants received 40 mg of IV cibisatamab QW without OB pre-treatment for the first 3 administrations, followed by Q3W administrations of up to 600 mg.

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

Dosage and administration details:

Participants received IV cibisatamab QW for the first 3 administrations, followed by Q3W administrations (Cycle 1 = 40 mg QW, Cycle 2 = 150 mg QW, Cycle 3 = 300 mg QW, Cycle 4-onwards = 600 mg Q3W).

Arm title	Cibisatamab QW CRC with OB

Arm description:

Participants received 135-300 mg of IV cibasatamab QW after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).

Arm type	Experimental

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

Dosage and administration details:

Participants received 135-300 mg of IV cibasatamab QW after pretreatment with obinutuzumab on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).

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

Dosage and administration details:

Participants received IV obinutuzumab pretreatment on Day -13 (2000 mg) or on Days -13 and -12 (1000 mg), followed by 135-300 mg of IV cibasatamab QW.

Arm title	Cibisatamab Q3W CRC with OB

Arm description:

Participants received 40-60 mg of IV cibasatamab Q3W after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).

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

Dosage and administration details:

Participants received 40-60 mg of IV cibasatamab Q3W after pretreatment with obinutuzumab on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).

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

Dosage and administration details:

Participants received IV obinutuzumab pretreatment on Day -13 (2000 mg) or on Days -13 and -12 (1000 mg), followed by 40-60 mg of IV cibasatamab Q3W.

Arm title	Cibisatamab Bile Duct

Arm description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

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

Dosage and administration details:

Participants received IV cibisatamab QW or Q3W.

Arm title	Cibisatamab Breast

Arm description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

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

Dosage and administration details:

Participants received IV cibisatamab QW or Q3W.

Arm title	Cibisatamab Lung

Arm description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

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

Dosage and administration details:

Participants received IV cibisatamab QW or Q3W.

Arm title	Cibisatamab Pancreatic

Arm description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

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

Dosage and administration details:

Participants received IV cibisatamab QW or Q3W.

Arm title	Cibisatamab Other

Arm description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

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

Dosage and administration details:

Participants received IV cibisatamab QW or Q3W.

Arm title	Cibisatamab Alone

Arm description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

Arm type	Experimental

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

Dosage and administration details:

Participants received IV cibisatamab QW or Q3W.

Number of subjects in period 1	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB
Started	8	27	14
Completed	0	0	0
Not completed	8	27	14
Death	-	-	-
Physician decision	-	1	-
Adverse event, non-fatal	-	-	-
Progressive Disease	7	22	12
Unspecified	-	2	1
Consent withdrawn by subject	1	2	1

Number of subjects in period 1	Cibisatamab MAD 300-600 mg QW CRC without OB	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB
Started	10	14	24
Completed	0	0	0
Not completed	10	14	24
Death	1	3	1
Physician decision	-	-	-
Adverse event, non-fatal	1	1	1
Progressive Disease	6	9	20
Unspecified	-	-	1
Consent withdrawn by subject	2	1	1

Number of subjects in period 1	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB	Cibisatamab Bile Duct
Started	10	14	2
Completed	0	0	0
Not completed	10	14	2
Death	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	1	1	-
Progressive Disease	9	11	2
Unspecified	-	1	-

Consent withdrawn by subject	-	1	-

Number of subjects in period 1	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Started	2	4	8
Completed	0	0	0
Not completed	2	4	8
Death	-	-	1
Physician decision	-	-	-
Adverse event, non-fatal	-	1	-
Progressive Disease	2	2	5
Unspecified	-	-	1
Consent withdrawn by subject	-	1	1

Number of subjects in period 1	Cibisatamab Other	Cibisatamab Alone
Started	6	6
Completed	0	0
Not completed	6	6
Death	-	2
Physician decision	1	-
Adverse event, non-fatal	-	-
Progressive Disease	5	1
Unspecified	-	1
Consent withdrawn by subject	-	2

Baseline characteristics

Reporting groups

Reporting group title	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)
Reporting group description:	
Participants with colorectal cancer (CRC) received a single administration of up to 2.5 mg intravenous (IV) cibisatamab without OB pre-treatment	
Reporting group title	Cibisatamab MAD 5-60 mg QW CRC without OB
Reporting group description:	
Participants with CRC received up to 60 mg of IV cibisatamab QW without OB pre-treatment.	
Reporting group title	Cibisatamab MAD 90-200 mg QW CRC without OB
Reporting group description:	
Participants with CRC received up to 200 mg of IV cibisatamab QW without OB pre-treatment.	
Reporting group title	Cibisatamab MAD 300-600 mg QW CRC without OB
Reporting group description:	
Participants with CRC received up to 600 mg of IV cibisatamab QW without OB pre-treatment.	
Reporting group title	Cibisatamab Step Up A/B CRC without OB
Reporting group description:	
Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 100% of the previous dose until the DLT criteria for that dose level was met (Cohort A). Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 150% of the previous dose up to 200 mg, and then QW by up to 100% until the DLT criteria for that dose was met (Cohort B).	
Reporting group title	Cibisatamab Step Up C CRC without OB
Reporting group description:	
Participants received 40 mg of IV cibisatamab QW without OB pre-treatment for the first 3 administrations, followed by Q3W administrations of up to 600 mg.	
Reporting group title	Cibisatamab QW CRC with OB
Reporting group description:	
Participants received 135-300 mg of IV cibasatamab QW after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).	
Reporting group title	Cibisatamab Q3W CRC with OB
Reporting group description:	
Participants received 40-60 mg of IV cibasatamab Q3W after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).	
Reporting group title	Cibisatamab Bile Duct
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Breast
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Lung
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Pancreatic
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Other
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	

Reporting group title	Cibisatamab Alone

Reporting group description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

Reporting group values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB
Number of subjects	8	27	14
Age Categorical Units: Subjects			
Adults (18-64 years)	6	15	8
From 65-84 years	2	12	6
Age Continuous Units: years			
arithmetic mean	56.0	61.1	62.9
standard deviation	± 10.0	± 12.7	± 5.4
Gender Categorical Units: Subjects			
Female	1	9	6
Male	7	18	8
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	8	27	14
Other	0	0	0
Unknown	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	4	3
Not Hispanic or Latino	8	16	10
Not Stated	0	0	1
Unknown	0	7	0

Reporting group values	Cibisatamab MAD 300-600 mg QW CRC without OB	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB
Number of subjects	10	14	24
Age Categorical Units: Subjects			
Adults (18-64 years)	5	10	16
From 65-84 years	5	4	8
Age Continuous Units: years			
arithmetic mean	62.2	61.1	58.8
standard deviation	± 11.5	± 7.4	± 11.3
Gender Categorical Units: Subjects			
Female	6	6	9
Male	4	8	15

Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	10	14	24
Other	0	0	0
Unknown	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	1	3
Not Hispanic or Latino	3	13	21
Not Stated	1	0	0
Unknown	2	0	0

Reporting group values	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB	Cibisatamab Bile Duct
Number of subjects	10	14	2
Age Categorical Units: Subjects			
Adults (18-64 years)	7	12	2
From 65-84 years	3	2	0
Age Continuous Units: years			
arithmetic mean	57.0	54.0	53.5
standard deviation	± 13.2	± 11.7	± 3.5
Gender Categorical Units: Subjects			
Female	3	5	1
Male	7	9	1
Race Units: Subjects			
Asian	0	1	0
Black or African American	0	2	0
White	10	9	2
Other	0	1	0
Unknown	0	1	0
Ethnicity Units: Subjects			
Hispanic or Latino	2	1	0
Not Hispanic or Latino	4	12	2
Not Stated	0	0	0
Unknown	4	1	0

Reporting group values	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Number of subjects	2	4	8
Age Categorical Units: Subjects			
Adults (18-64 years)	2	4	4
From 65-84 years	0	0	4

Age Continuous Units: years			
arithmetic mean	52.0	52.8	63.4
standard deviation	± 3.5	± 9.5	± 4.8
Gender Categorical Units: Subjects			
Female	2	3	5
Male	0	1	3
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	2	4	8
Other	0	0	0
Unknown	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	1	1	6
Not Hispanic or Latino	1	2	2
Not Stated	0	0	0
Unknown	0	1	0

Reporting group values	Cibisatamab Other	Cibisatamab Alone	Total
Number of subjects	6	6	149
Age Categorical Units: Subjects			
Adults (18-64 years)	5	4	100
From 65-84 years	1	2	49
Age Continuous Units: years			
arithmetic mean	51.3	59.0	
standard deviation	± 15.6	± 9.5	-
Gender Categorical Units: Subjects			
Female	3	2	61
Male	3	4	88
Race Units: Subjects			
Asian	0	0	1
Black or African American	0	0	2
White	6	6	144
Other	0	0	1
Unknown	0	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	4	2	32
Not Hispanic or Latino	2	3	99
Not Stated	0	0	2
Unknown	0	1	16

End points

End points reporting groups

Reporting group title	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)
Reporting group description:	
Participants with colorectal cancer (CRC) received a single administration of up to 2.5 mg intravenous (IV) cibisatamab without OB pre-treatment	
Reporting group title	Cibisatamab MAD 5-60 mg QW CRC without OB
Reporting group description:	
Participants with CRC received up to 60 mg of IV cibisatamab QW without OB pre-treatment.	
Reporting group title	Cibisatamab MAD 90-200 mg QW CRC without OB
Reporting group description:	
Participants with CRC received up to 200 mg of IV cibisatamab QW without OB pre-treatment.	
Reporting group title	Cibisatamab MAD 300-600 mg QW CRC without OB
Reporting group description:	
Participants with CRC received up to 600 mg of IV cibisatamab QW without OB pre-treatment.	
Reporting group title	Cibisatamab Step Up A/B CRC without OB
Reporting group description:	
Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 100% of the previous dose until the DLT criteria for that dose level was met (Cohort A). Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 150% of the previous dose up to 200 mg, and then QW by up to 100% until the DLT criteria for that dose was met (Cohort B).	
Reporting group title	Cibisatamab Step Up C CRC without OB
Reporting group description:	
Participants received 40 mg of IV cibisatamab QW without OB pre-treatment for the first 3 administrations, followed by Q3W administrations of up to 600 mg.	
Reporting group title	Cibisatamab QW CRC with OB
Reporting group description:	
Participants received 135-300 mg of IV cibasatamab QW after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).	
Reporting group title	Cibisatamab Q3W CRC with OB
Reporting group description:	
Participants received 40-60 mg of IV cibasatamab Q3W after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).	
Reporting group title	Cibisatamab Bile Duct
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Breast
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Lung
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Pancreatic
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Reporting group title	Cibisatamab Other
Reporting group description:	
Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	

Reporting group title	Cibisatamab Alone
Reporting group description: Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	
Subject analysis set title	ADA-Negative PK Population
Subject analysis set type	Sub-group analysis
Subject analysis set description: ADA-negative participants treated with an initial cibisatamab dose of >20 mg.	
Subject analysis set title	PK Population
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants that received at least one dose of study drug.	
Subject analysis set title	Obinutuzumab PK Population
Subject analysis set type	Sub-group analysis
Subject analysis set description: Participants that received obinutuzumab pre-treatment with eligible PK samples.	
Subject analysis set title	Cibisatamab 2.5 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 5 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 10 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 20 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 40 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 60mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 90 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 100 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 135 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	

Subject analysis set title	Cibisatamab 200 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 300 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 400 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 600 mg MAD
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II	
Subject analysis set title	Cibisatamab 40 mg Step-Up Cohort A
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II of the study Cohorts A (40/80/160/300/400/600/800/1200 mg IV cibisatamab QW) and B (40/100/200/400/800/1200 mg IV cibisatamab QW).	
Subject analysis set title	Cibisatamab 40 mg Step-Up Cohort B
Subject analysis set type	Safety analysis
Subject analysis set description: Participants in dose escalation Part II of the study Cohorts A (40/80/160/300/400/600/800/1200 mg IV cibisatamab QW) and B (40/100/200/400/800/1200 mg IV cibisatamab QW).	

Primary: Percentage of Participants with Adverse Events (AEs) or Serious Adverse Events (SAEs)

End point title	Percentage of Participants with Adverse Events (AEs) or Serious Adverse Events (SAEs)[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: 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 formal statistical analyses were planned for this Phase I study.

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	27	14	10
Units: Percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	24	10	14
Units: Percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	8
Units: Percentage of participants				
number (not applicable)	100	100	100	100

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Percentage of participants				
number (not applicable)	100	50		

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

End point description:

9999 = population not included for the given category

End point type	Primary

End point timeframe:

Day 1 - 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 formal statistical analyses were planned for this Phase I study.

End point values	Cibisatamab 2.5 mg MAD	Cibisatamab 5 mg MAD	Cibisatamab 10 mg MAD	Cibisatamab 20 mg MAD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	6	3	4
Units: Percentage of Participants				
number (not applicable)				
MTD	0	0	0	0
Late Cycle MTD	9999	9999	9999	9999

End point values	Cibisatamab 40 mg MAD	Cibisatamab 60mg MAD	Cibisatamab 90 mg MAD	Cibisatamab 100 mg MAD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	12	7	3	5
Units: Percentage of Participants				
number (not applicable)				
MTD	8.3	14.3	0	0
Late Cycle MTD	9999	9999	9999	9999

End point values	Cibisatamab 135 mg MAD	Cibisatamab 200 mg MAD	Cibisatamab 300 mg MAD	Cibisatamab 400 mg MAD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	5	5	7
Units: Percentage of Participants				
number (not applicable)				
MTD	0	0	20.0	0
Late Cycle MTD	9999	9999	9999	9999

End point values	Cibisatamab 600 mg MAD	Cibisatamab 40 mg Step-Up Cohort A	Cibisatamab 40 mg Step-Up Cohort B	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	12	10	
Units: Percentage of Participants				
number (not applicable)				
MTD	100.0	9999	9999	
Late Cycle MTD	9999	0	10.0	

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Anti-Drug Antibodies (ADAs) Against Cibisatamab

End point title	Percentage of Participants with Anti-Drug Antibodies (ADAs) Against Cibisatamab[3]

End point description:

End point type	Primary

End point timeframe:

Cycle 1 Day 1 up to 60 months

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 formal statistical analyses were planned for this Phase I study.

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	26	14	8
Units: Percentage of Participants				
number (not applicable)	50.0	73.1	64.3	25.0

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	24	10	14
Units: Percentage of Participants				
number (not applicable)	45.5	37.5	20.0	50.0

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	7
Units: Percentage of Participants				
number (not applicable)	50.0	0	50.0	71.4

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	0[4]		
Units: Percentage of Participants				
number (not applicable)	16.7			

Notes:

[4] - There were no post-baseline evaluable participants for this arm.

Statistical analyses

No statistical analyses for this end point

Primary: Late Cycle MTD of Cibisatamab Without Obinutuzumab Pretreatment for the Step-Up Dosing Regimen

End point title	Late Cycle MTD of Cibisatamab Without Obinutuzumab Pretreatment for the Step-Up Dosing Regimen[5]

End point description:

End point type	Primary

End point timeframe:

Days 1-7 of each 7-day Cycle of Part II for as long as the dose was escalated QW (up to approximately 60 months)

Notes:

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

End point values	Cibisatamab 40 mg Step-Up Cohort A	Cibisatamab 40 mg Step-Up Cohort B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	10		
Units: mg				
number (not applicable)	400	400		

Statistical analyses

No statistical analyses for this end point

Primary: MTD of Cibisatamab With or Without Obinutuzumab Pretreatment for the Step-Up Dosing Regimen

End point title	MTD of Cibisatamab With or Without Obinutuzumab Pretreatment for the Step-Up Dosing Regimen[6]

End point description:

End point type	Primary

End point timeframe:

Days 1-7 of each 7-day Cycle of Part II for as long as the dose was escalated QW (up to approximately 60 months)

Notes:

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

End point values	Cibisatamab 40 mg Step-Up Cohort A	Cibisatamab 40 mg Step-Up Cohort B		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[7]	0[8]		
Units: mg				
number (not applicable)				

Notes:

[7] - There was insufficient data to report on this parameter.

[8] - There was insufficient data to report on this parameter.

Statistical analyses

No statistical analyses for this end point

Primary: Maximum Serum Concentration (Cmax) of Cibisatamab

End point title	Maximum Serum Concentration (Cmax) of Cibisatamab[9]

End point description:

Median is reported. Full ranges are 5th (min) and 95th (max) percentiles.

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

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

End point values	PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	103[10]			
Units: ug/mL				
median (full range (min-max))				
Dose 40 mg (N=52)	9.95 (7.39 to 13.97)			
Dose 60 mg (N=21)	15.33 (11.35 to 18.98)			
Dose 100 mg (N=4)	23.93 (20.64 to 30.89)			
Dose 135 mg (N=6)	31.98 (26.37 to 33.6)			
Dose 200 mg (N=6)	56.93 (42.41 to 113.7)			
Dose 300 mg (N=6)	89.26 (74.85 to 99.35)			
Dose 400 mg (N=5)	108.43 (94.27 to 160.33)			

Notes:

[10] - Full range = 5th (min) - 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Primary: Area Under the Concentration vs Time Curve (AUC) of Cibisatamab

End point title	Area Under the Concentration vs Time Curve (AUC) of Cibisatamab[11]

End point description:

Median is reported. Full range = 5th (min) and 95th (max) percentiles.

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

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

End point values	PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	103[12]			
Units: ug*h/mL				
median (full range (min-max))				
Dose 40 mg (N=52)	393 (156 to 651)			
Dose 60 mg (N=21)	416 (200 to 1212)			
Dose 100 mg (N=4)	492 (416 to 1233)			
Dose 135 mg (N=6)	812 (467 to 1313)			
Dose 200 mg (N=6)	2298 (908 to 3475)			
Dose 300 mg (N=6)	2564 (1349 to 3590)			
Dose 400 mg (N=5)	5306 (3325 to 5675)			

Notes:

[12] - Full range = 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Primary: Half-Life (t1/2) of Cibisatamab

End point title	Half-Life (t1/2) of Cibisatamab[13]

End point description:

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

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

End point values	PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	145			
Units: days				
number (not applicable)	2			

Statistical analyses

No statistical analyses for this end point

Primary: Clearance (CL) of Cibisatamab

End point title	Clearance (CL) of Cibisatamab[14]

End point description:

Drug clearance describes the rate at which an active substance leaves the body and is defined as the rate of drug elimination divided by the substance drug concentration.
Median is reported. Full range = 5th (min) and 95th (max) percentiles.

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

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

End point values	ADA-Negative PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	59[15]			
Units: L/h				
median (full range (min-max))	0.063 (0.033 to 0.229)			

Notes:

[15] - Full range = 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Primary: Volume of Distribution at Steady State (Vss) of Cibisatamab

End point title	Volume of Distribution at Steady State (Vss) of Cibisatamab[16]

End point description:

Vss indicates the amount of drug in the body.
Median is reported. Full range = 5th (min) and 95th (max) percentiles.

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

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

End point values	ADA-Negative PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	59[17]			
Units: Liters (L)				
median (full range (min-max))	8.25 (6.28 to 10.66)			

Notes:

[17] - Full range = 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Primary: Minimum Drug Concentration (Cmin) of Cibisatamab

End point title	Minimum Drug Concentration (Cmin) of Cibisatamab[18]

End point description:

Median is reported. Full range = 5th (min) and 95th (max) percentiles.

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

[18] - 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 formal statistical analyses were planned for this Phase I study.

End point values	PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	103[19]			
Units: ug/mL				
median (full range (min-max))				
Dose 40 mg (N=52)	0.48 (0.05 to 1.47)			
Dose 60 mg (N=21)	0.32 (0.07 to 2.85)			
Dose 100 mg (N=4)	0.24 (0.18 to 1.84)			
Dose 135 mg (N=6)	0.39 (0.13 to 1.71)			
Dose 200 mg (N=6)	0.45 (0.19 to 7.04)			
Dose 300 mg (N=6)	0.65 (0.55 to 5.48)			
Dose 400 mg (N=5)	3.94 (2.32 to 11.55)			

Notes:

[19] - Full range = 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Primary: Cmax of Obinutuzumab

End point title	Cmax of Obinutuzumab[20]

End point description:

Median is reported. Full range = 5th (min) and 95th (max) percentiles.

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

[20] - 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 formal statistical analyses were planned for this Phase I study.

End point values	Obinutuzumab PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	33[21]			
Units: ug/mL				
median (full range (min-max))	583 (331 to 1250)			

Notes:

[21] - Full range = 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Primary: Cmin of Obinutuzumab

End point title	Cmin of Obinutuzumab[22]

End point description:

Median is reported. Full range = 5th (min) and 95th (max) percentiles.

End point type	Primary

End point timeframe:

Up to 60 months

Notes:

[22] - 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 formal statistical analyses were planned for this Phase I study.

End point values	Obinutuzumab PK Population			
Subject group type	Subject analysis set			
Number of subjects analysed	33[23]			
Units: ug/mL				
median (full range (min-max))	65.7 (5.83 to 203)			

Notes:

[23] - Full range = 5th (min) and 95th (max) percentiles.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with an Objective Response of Complete Response (CR) or Partial Response (PR) According to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1

End point title	Percentage of Participants with an Objective Response of Complete Response (CR) or Partial Response (PR) According to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1

End point description:

End point type	Secondary

End point timeframe:

Up to 60 months

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	27	14	10
Units: Percentage of participants				
number (confidence interval 90%)	0 (0 to 31.2)	0 (0 to 10.5)	7.1 (0.4 to 29.7)	0 (0 to 25.9)

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	24	10	14
Units: Percentage of participants				
number (confidence interval 90%)	14.3 (2.6 to 38.5)	4.2 (0.2 to 18.3)	10.0 (0.5 to 39.4)	0 (0 to 19.3)

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	8
Units: Percentage of participants				
number (confidence interval 90%)	0 (0 to 77.6)	0 (0 to 77.6)	0 (0 to 52.7)	12.5 (0.6 to 47.1)

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Percentage of participants				
number (confidence interval 90%)	0 (0 to 39.3)	0 (0 to 39.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) According to RECIST v1.1

End point title	Duration of Response (DOR) According to RECIST v1.1[24]

End point description:

End point type	Secondary

End point timeframe:

Up to 60 months

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: End point analysis was limited to the specified reported arms.

End point values	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	14	14	24
Units: Months				
median (full range (min-max))	0.9 (0.9 to 0.9)	3.1 (3.1 to 3.1)	6.5 (5.6 to 7.3)	11.1 (11.1 to 11.1)

End point values	Cibisatamab QW CRC with OB	Cibisatamab Pancreatic		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	8		
Units: Months				
median (full range (min-max))	7.4 (7.4 to 7.4)	3.9 (3.9 to 3.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Stable Disease (SD) According to RECIST v1.1

End point title	Percentage of Participants with Stable Disease (SD) According to RECIST v1.1

End point description:

End point type	Secondary

End point timeframe:

Up to 60 months

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	27	14	10
Units: Percentage of participants				
number (confidence interval 90%)	37.5 (11.1 to 71.1)	37.0 (21.7 to 54.7)	14.3 (2.6 to 38.5)	30.0 (8.7 to 60.7)

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	24	10	14
Units: Percentage of participants				
number (confidence interval 90%)	35.7 (15.3 to 61.0)	25.0 (11.5 to 43.5)	30.0 (8.7 to 60.7)	7.1 (0.4 to 29.7)

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	8
Units: Percentage of participants				
number (confidence interval 90%)	50.0 (2.5 to 97.5)	50.0 (2.5 to 97.5)	50.0 (9.8 to 90.2)	25.0 (4.6 to 60.0)

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Percentage of participants				
number (confidence interval 90%)	16.7 (0.9 to 58.2)	0 (0 to 39.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Disease Control, Defined as PR+CR+SD, According to RECIST v1.1

End point title	Percentage of Participants with Disease Control, Defined as PR+CR+SD, According to RECIST v1.1

End point description:

End point type	Secondary

End point timeframe:

Up to 60 months

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	27	14	10
Units: Percentage of participants				
number (confidence interval 90%)	37.5 (11.1 to 71.1)	37.0 (21.7 to 54.7)	21.4 (6.1 to 46.6)	30.0 (8.7 to 60.7)

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	24	10	14
Units: Percentage of participants				
number (confidence interval 90%)	50.0 (26.4 to 73.6)	29.2 (14.6 to 47.9)	40.0 (15.0 to 69.6)	7.1 (0.4 to 29.7)

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	8
Units: Percentage of participants				

number (confidence interval 90%)	50.0 (2.5 to 97.5)	50.0 (2.5 to 97.5)	50.0 (9.8 to 90.2)	37.5 (11.1 to 71.1)

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Percentage of participants				
number (confidence interval 90%)	16.7 (0.9 to 58.2)	0 (0 to 39.3)		

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:

Up to 60 months

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	27	14	10
Units: Months				
median (full range (min-max))	2.6 (0.8 to 8.5)	2.8 (0.0 to 23.0)	2.3 (0.0 to 11.1)	3.4 (0.1 to 35.2)

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	24	10	14
Units: Months				
median (full range (min-max))	3.5 (0.1 to 9.0)	1.9 (0.5 to 12.9)	1.8 (0.7 to 9.2)	1.9 (0.0 to 4.3)

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	8
Units: Months				
median (full range (min-max))	2.6 (1.8 to 3.4)	1.7 (1.2 to 2.3)	4.6 (0.9 to 16.9)	1.7 (0.9 to 5.6)

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Months				
median (full range (min-max))	2.5 (1.1 to 5.3)	1.8 (0.0 to 9.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Activated Intra-Tumoral Cells

End point title	Change from Baseline in Activated Intra-Tumoral Cells

End point description:

End point type	Secondary

End point timeframe:

Up to 60 months

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[25]	0[26]	0[27]	0[28]
Units: Not Applicable				
number (not applicable)				

Notes:

[25] - Endpoint was not included in final analysis.

[26] - Endpoint was not included in final analysis.

[27] - Endpoint was not included in final analysis.

[28] - Endpoint was not included in final analysis.

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[29]	0[30]	0[31]	0[32]
Units: Not Applicable				
number (not applicable)				

Notes:

[29] - Endpoint was not included in final analysis.

[30] - Endpoint was not included in final analysis.

[31] - Endpoint was not included in final analysis.

[32] - Endpoint was not included in final analysis.

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[33]	0[34]	0[35]	0[36]
Units: Not Applicable				
number (not applicable)				

Notes:

[33] - Endpoint was not included in final analysis.

[34] - Endpoint was not included in final analysis.

[35] - Endpoint was not included in final analysis.

[36] - Endpoint was not included in final analysis.

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[37]	0[38]		
Units: Not Applicable				
number (not applicable)				

Notes:

[37] - Endpoint was not included in final analysis.

[38] - Endpoint was not included in final analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)

End point title	Best Overall Response (BOR)

End point description:

BOR is defined as the best confirmed response recorded from the start of treatment until disease progression, recurrence, or death, whichever occurs first.

End point type	Secondary

End point timeframe:

Up to 60 months

End point values	Cibisatamab SAD+MAD <=2.5 mg QW CRC without Obinutuzumab (OB)	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB	Cibisatamab MAD 300-600 mg QW CRC without OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	27	14	10
Units: Percentage of participants				
number (confidence interval 90%)				
Complete Response	0 (0.0 to 31.2)	0 (0.0 to 10.5)	0 (0.0 to 19.3)	0 (0.0 to 25.9)
Partial Response	0 (0.0 to 31.2)	0 (0.0 to 10.5)	7.1 (0.4 to 29.7)	0 (0.0 to 25.9)
Stable Disease	37.5 (11.1 to 71.1)	37.0 (21.7 to 54.7)	14.3 (2.6 to 38.5)	30.0 (8.7 to 60.7)

End point values	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	24	10	14
Units: Percentage of participants				
number (confidence interval 90%)				
Complete Response	0 (0.0 to 19.3)	0 (0.0 to 11.7)	0 (0.0 to 25.9)	0 (0.0 to 19.3)
Partial Response	14.3 (2.6 to 38.5)	4.2 (0.2 to 18.3)	10.0 (0.5 to 39.4)	0 (0.0 to 19.3)
Stable Disease	35.7 (15.3 to 61.0)	25.0 (11.5 to 43.5)	30.0 (8.7 to 60.7)	7.1 (0.4 to 29.7)

End point values	Cibisatamab Bile Duct	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	8
Units: Percentage of participants				
number (confidence interval 90%)				
Complete Response	0 (0.0 to 77.6)	0 (0.0 to 77.6)	0 (0.0 to 52.7)	0 (0.0 to 31.2)
Partial Response	0 (0.0 to 77.6)	0 (0.0 to 77.6)	0 (0.0 to 52.7)	12.5 (0.6 to 47.1)
Stable Disease	50.0 (2.5 to 97.5)	50.0 (2.5 to 97.5)	50.0 (9.8 to 90.2)	25.0 (4.6 to 60.0)

End point values	Cibisatamab Other	Cibisatamab Alone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Percentage of participants				
number (confidence interval 90%)				
Complete Response	0 (0.0 to 39.3)	0 (0.0 to 39.3)		

Partial Response	0 (0.0 to 39.3)	0 (0.0 to 39.3)		
Stable Disease	16.7 (0.9 to 58.2)	0 (0.0 to 39.3)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From study drug initiation until 28 days after the last dose of study drug, or until initiation of new systemic anti-cancer therapy, whichever occurred first

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Cibisatamab SAD+MAD <=2.5 mg QW CRC without OB

Reporting group description:

Participants with colorectal cancer (CRC) received a single administration of up to 2.5 mg intravenous (IV) cibisatamab without OB pre-treatment

Reporting group title	Cibisatamab MAD 5-60 mg QW CRC without OB

Reporting group description:

Participants with CRC received up to 60 mg of IV cibisatamab QW without OB pre-treatment.

Reporting group title	Cibisatamab MAD 90-200 mg QW CRC without OB

Reporting group description:

Participants with CRC received up to 200 mg of IV cibisatamab QW without OB pre-treatment.

Reporting group title	Cibisatamab MAD 300-600 mg QW CRC without OB

Reporting group description:

Participants with CRC received up to 600 mg of IV cibisatamab QW without OB pre-treatment.

Reporting group title	Cibisatamab Step Up A/B CRC without OB

Reporting group description:

Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 100% of the previous dose until the DLT criteria for that dose level was met (Cohort A). Participants received a starting dose of 40 mg IV cibisatamab and escalated QW by up to 150% of the previous dose up to 200 mg, and then QW by up to 100% until the DLT criteria for that dose was met (Cohort B).

Reporting group title	Cibisatamab Step Up C CRC without OB

Reporting group description:

Participants received 40 mg of IV cibisatamab QW without OB pre-treatment for the first 3 administrations, followed by Q3W administrations of up to 600 mg.

Reporting group title	Cibisatamab QW CRC with OB

Reporting group description:

Participants received 135-300 mg of IV cibasatamab QW after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).

Reporting group title	Cibisatamab Q3W CRC with OB

Reporting group description:

Participants received 40-60 mg of IV cibasatamab Q3W after pre-treatment with IV OB on Day -12 (2000 mg) or on Days -13 and -12 (1000 mg).

Reporting group title	Cibisatamab Bile Duct

Reporting group description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

Reporting group title	Cibisatamab Breast

Reporting group description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).

Reporting group title	Cibisatamab Lung

Reporting group description:

Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by

prior cohort(s).

Reporting group title	Cibisatamab Pancreatic
Reporting group description: Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	

Reporting group title	Cibisatamab Other
Reporting group description: Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	

Reporting group title	Cibisatamab Alone
Reporting group description: Participants received IV cibisatamab QW or Q3W with or without OB pre-treatment at a dose defined by prior cohort(s).	

Serious adverse events	Cibisatamab SAD+MAD <=2.5 mg QW CRC without OB	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)	17 / 27 (62.96%)	7 / 14 (50.00%)
number of deaths (all causes)	8	21	12
number of deaths resulting from adverse events			
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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)			
Tumour inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tumour thrombosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localized oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	7 / 27 (25.93%)	4 / 14 (28.57%)
occurrences causally related to treatment / all	0 / 0	7 / 7	8 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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
Aspartate aminotransferase increase			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (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 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decrease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (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
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)

occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (12.50%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	2 / 14 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences causally related to	0 / 0	0 / 1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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			
Arthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (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
Liver abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
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	Cibisatamab MAD 300-600 mg QW CRC without OB	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 10 (80.00%)	11 / 14 (78.57%)	19 / 24 (79.17%)
number of deaths (all causes)	9	13	16
number of deaths resulting from adverse events			
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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)			
Tumour inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
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 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localized oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	3 / 10 (30.00%)	5 / 14 (35.71%)	11 / 24 (45.83%)
occurrences causally related to treatment / all	4 / 4	12 / 12	16 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increase			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
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 creatinine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decrease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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			
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (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
Spinal cord compression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 24 (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
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)

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 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (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
Pneumoperitoneum			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences causally related to	0 / 1	0 / 1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (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
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (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 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
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 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB	Cibisatamab Bile Duct
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	9 / 14 (64.29%)	1 / 2 (50.00%)
number of deaths (all causes)	10	8	2
number of deaths resulting from adverse events			
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tumour thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localized oedema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	7 / 10 (70.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	7 / 7	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increase			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decrease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 10 (20.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to	0 / 2	0 / 1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	3 / 4 (75.00%)	7 / 8 (87.50%)
number of deaths (all causes)	2	4	7
number of deaths resulting from adverse events			
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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)			
Tumour inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tumour thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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			
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localized oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	2 / 4 (50.00%)	2 / 8 (25.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
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 increase			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
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 bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decrease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (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
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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			
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (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
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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			
Arthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Tracheobronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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 / 4 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
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	Cibisatamab Other	Cibisatamab Alone	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	2 / 6 (33.33%)	
number of deaths (all causes)	5	6	
number of deaths resulting from adverse events			
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Tumour thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localized oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increase			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decrease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	

occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	

occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumoperitoneum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to	0 / 0	0 / 0	

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	

occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Cibisatamab SAD+MAD <=2.5 mg QW CRC without OB	Cibisatamab MAD 5-60 mg QW CRC without OB	Cibisatamab MAD 90-200 mg QW CRC without OB
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	27 / 27 (100.00%)	14 / 14 (100.00%)
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 8 (12.50%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	1	3	1
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	4 / 14 (28.57%)

occurrences (all)	0	1	4
Phlebitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vasculitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Venous thrombosis limb			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 8 (12.50%)	8 / 27 (29.63%)	2 / 14 (14.29%)
occurrences (all)	1	17	2
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 8 (50.00%)	12 / 27 (44.44%)	4 / 14 (28.57%)
occurrences (all)	11	27	15
Chest discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 8 (0.00%)	13 / 27 (48.15%)	5 / 14 (35.71%)
occurrences (all)	0	26	5
Face oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 8 (12.50%)	4 / 27 (14.81%)	3 / 14 (21.43%)

occurrences (all)	1	5	4
Feeling hot			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Infusion site extravasation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	4 / 14 (28.57%)
occurrences (all)	0	0	4
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	4 / 8 (50.00%)	21 / 27 (77.78%)	7 / 14 (50.00%)
occurrences (all)	20	50	18
Swelling face			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)

occurrences (all)	0	0	0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 27 (11.11%)	1 / 14 (7.14%)
occurrences (all)	0	3	1
Mental disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Prostatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Uterine pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)

occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	12 / 27 (44.44%)	13 / 14 (92.86%)
occurrences (all)	0	20	31
Limb injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Post-traumatic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Wound			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	6 / 27 (22.22%)	2 / 14 (14.29%)
occurrences (all)	2	8	4
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	10 / 27 (37.04%)	2 / 14 (14.29%)

occurrences (all)	1	14	4
Blood albumin decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	4 / 27 (14.81%)	3 / 14 (21.43%)
occurrences (all)	0	5	4
Blood bilirubin increased			
subjects affected / exposed	2 / 8 (25.00%)	5 / 27 (18.52%)	4 / 14 (28.57%)
occurrences (all)	2	8	7
Blood calcium decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood cholesterol increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	3 / 27 (11.11%)	0 / 14 (0.00%)
occurrences (all)	0	8	0
Blood iron decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	2 / 14 (14.29%)
occurrences (all)	0	2	2
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Neutrophil count decreased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	2 / 14 (14.29%)
occurrences (all)	0	2	3
Serum ferritin decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Blood cholesterol decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Congestive cardiovascular insufficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Catarhh			
subjects affected / exposed	2 / 8 (25.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Cough			
subjects affected / exposed	4 / 8 (50.00%)	8 / 27 (29.63%)	4 / 14 (28.57%)
occurrences (all)	4	11	4
Dry throat			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	3 / 27 (11.11%)	1 / 14 (7.14%)
occurrences (all)	0	4	1
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Laryngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	0	2	1
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Throat irritation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 8 (37.50%)	12 / 27 (44.44%)	8 / 14 (57.14%)
occurrences (all)	7	15	11
Bandaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 8 (12.50%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	1	4	5
Dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	5 / 27 (18.52%)	3 / 14 (21.43%)
occurrences (all)	0	5	3
Facial nerve disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	2 / 8 (25.00%)	4 / 27 (14.81%)	0 / 14 (0.00%)
occurrences (all)	4	6	0
Migraine			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)

occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Taste disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Diplopia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Macular oedema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Tinnitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 8 (12.50%)	1 / 27 (3.70%)	0 / 14 (0.00%)

occurrences (all)	1	1	0
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	0	2	2
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 8 (12.50%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	1	2	1
Ascites			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	4 / 27 (14.81%)	2 / 14 (14.29%)
occurrences (all)	0	4	2
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	12 / 27 (44.44%)	8 / 14 (57.14%)
occurrences (all)	6	34	16
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)

occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lumbar hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 8 (25.00%)	10 / 27 (37.04%)	6 / 14 (42.86%)
occurrences (all)	3	22	9
Odynophagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)

occurrences (all)	0	2	0
Subileus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tongue oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	10 / 27 (37.04%)	6 / 14 (42.86%)
occurrences (all)	1	17	7
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	7
Hydronephrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nephropathy toxic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Renal failure			

subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	4
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatic function abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ocular icterus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	3 / 27 (11.11%)	0 / 14 (0.00%)

occurrences (all)	0	7	0
Eczema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Hyperkeratosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Palmar erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Petechiae			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pruritis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Rash macular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	4
Rash pruritic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Skin disorder			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 8 (0.00%)	6 / 27 (22.22%)	4 / 14 (28.57%)
occurrences (all)	0	10	5
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	4 / 27 (14.81%)	1 / 14 (7.14%)
occurrences (all)	0	11	3
Arthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	3 / 8 (37.50%)	6 / 27 (22.22%)	3 / 14 (21.43%)
occurrences (all)	4	6	4
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	3 / 27 (11.11%)	0 / 14 (0.00%)
occurrences (all)	0	4	0
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0

Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	3 / 27 (11.11%)	0 / 14 (0.00%)
occurrences (all)	0	4	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Polymyalgia rheumatica			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	8 / 27 (29.63%)	5 / 14 (35.71%)
occurrences (all)	0	8	6
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	4
Hyperglycaemia			
subjects affected / exposed	2 / 8 (25.00%)	3 / 27 (11.11%)	0 / 14 (0.00%)
occurrences (all)	2	5	0
Hyperkalaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	6 / 27 (22.22%)	7 / 14 (50.00%)
occurrences (all)	0	10	12
Hypocalcaemia			
subjects affected / exposed	3 / 8 (37.50%)	4 / 27 (14.81%)	2 / 14 (14.29%)
occurrences (all)	5	4	3
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 27 (11.11%)	3 / 14 (21.43%)
occurrences (all)	0	4	4
Hypomagnesaemia			
subjects affected / exposed	2 / 8 (25.00%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	8	2	1
Hyponatraemia			
subjects affected / exposed	4 / 8 (50.00%)	3 / 27 (11.11%)	4 / 14 (28.57%)
occurrences (all)	7	3	6
Hypophosphataemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 27 (7.41%)	2 / 14 (14.29%)
occurrences (all)	2	2	2
Hypouricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tetany			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			

subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	1 / 14 (7.14%)
occurrences (all)	0	1	2
Infections and infestations			
Bacterial translocation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Herpes virus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 8 (12.50%)	2 / 27 (7.41%)	2 / 14 (14.29%)
occurrences (all)	1	2	2

Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 27 (3.70%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 27 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	2 / 27 (7.41%)	1 / 14 (7.14%)
occurrences (all)	0	2	2

Non-serious adverse events	Cibisatamab MAD 300-600 mg QW CRC without OB	Cibisatamab Step Up A/B CRC without OB	Cibisatamab Step Up C CRC without OB
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	14 / 14 (100.00%)	24 / 24 (100.00%)
Vascular disorders			

Bloody discharge			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	1	3	0
Haematoma			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	6	0	0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	3 / 24 (12.50%)
occurrences (all)	0	1	3
Phlebitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	5 / 10 (50.00%)	2 / 14 (14.29%)	3 / 24 (12.50%)
occurrences (all)	12	2	4
Chest discomfort			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Chills			
subjects affected / exposed	3 / 10 (30.00%)	1 / 14 (7.14%)	7 / 24 (29.17%)
occurrences (all)	6	1	8
Face oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 10 (20.00%)	4 / 14 (28.57%)	8 / 24 (33.33%)
occurrences (all)	3	5	8
Feeling hot			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Mucosal inflammation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	3
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	8 / 10 (80.00%)	5 / 14 (35.71%)	12 / 24 (50.00%)
occurrences (all)	20	6	20
Swelling face			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Xerosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)

occurrences (all)	0	1	0
Mental disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Uterine pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	4 / 10 (40.00%)	11 / 14 (78.57%)	17 / 24 (70.83%)
occurrences (all)	4	41	35
Limb injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)

occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Wound			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	2	0	3
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	2 / 24 (8.33%)
occurrences (all)	1	1	3
Blood albumin decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	7	0	2
Blood calcium decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	4

Blood iron decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	3 / 14 (21.43%)	2 / 24 (8.33%)
occurrences (all)	0	3	3
Lymphocyte count decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	2 / 24 (8.33%)
occurrences (all)	0	1	7
Neutrophil count decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Serum ferritin decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Transaminases increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Urine output decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)

occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Blood cholesterol decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Cardiac failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Congestive cardiovascular insufficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Catarhh			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 10 (20.00%)	2 / 14 (14.29%)	7 / 24 (29.17%)

occurrences (all)	2	2	8
Dry throat			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	3 / 24 (12.50%)
occurrences (all)	2	0	3
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Laryngeal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)

occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 10 (50.00%)	4 / 14 (28.57%)	4 / 24 (16.67%)
occurrences (all)	5	6	7
Bandaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Disturbance in Attention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	3 / 24 (12.50%)
occurrences (all)	0	4	3

Dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	3 / 10 (30.00%)	3 / 14 (21.43%)	9 / 24 (37.50%)
occurrences (all)	6	4	12
Facial nerve disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	3
Migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Neuropathy peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Neurotoxicity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	1 / 24 (4.17%)
occurrences (all)	0	2	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Macular oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)

occurrences (all)	0	1	0

Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	2 / 10 (20.00%)	2 / 14 (14.29%)	4 / 24 (16.67%)
occurrences (all)	2	4	5
Abdominal pain lower			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 10 (10.00%)	2 / 14 (14.29%)	3 / 24 (12.50%)
occurrences (all)	1	3	5
Ascites			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)

occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 10 (20.00%)	2 / 14 (14.29%)	6 / 24 (25.00%)
occurrences (all)	3	2	6
Diarrhoea			
subjects affected / exposed	5 / 10 (50.00%)	6 / 14 (42.86%)	12 / 24 (50.00%)
occurrences (all)	14	19	24
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	5 / 24 (20.83%)
occurrences (all)	0	1	5
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lumbar hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 10 (40.00%)	3 / 14 (21.43%)	8 / 24 (33.33%)

occurrences (all)	4	7	13
Odynophagia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Pancreatitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	3 / 24 (12.50%)
occurrences (all)	0	0	3
Subileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Tongue oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 10 (50.00%)	1 / 14 (7.14%)	8 / 24 (33.33%)
occurrences (all)	5	1	13
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dysuria			

subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	2
Hydronephrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nephropathy toxic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Renal impairment			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Urinary retention			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hepatic function abnormal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Ocular icterus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	3
Dry skin			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
Eczema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Hyperkeratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	3 / 24 (12.50%)

occurrences (all)	0	0	3
Petechiae			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Pruritis			
subjects affected / exposed	1 / 10 (10.00%)	3 / 14 (21.43%)	4 / 24 (16.67%)
occurrences (all)	1	4	4
Rash			
subjects affected / exposed	2 / 10 (20.00%)	1 / 14 (7.14%)	4 / 24 (16.67%)
occurrences (all)	3	2	6
Rash macular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Skin exfoliation			
subjects affected / exposed	3 / 10 (30.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 10 (50.00%)	1 / 14 (7.14%)	2 / 24 (8.33%)
occurrences (all)	6	1	3

Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	3 / 24 (12.50%)
occurrences (all)	0	0	3
Back pain			
subjects affected / exposed	1 / 10 (10.00%)	2 / 14 (14.29%)	2 / 24 (8.33%)
occurrences (all)	1	5	2
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	3	1
Groin pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	3 / 24 (12.50%)
occurrences (all)	0	1	4
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	4 / 14 (28.57%)	1 / 24 (4.17%)
occurrences (all)	0	4	1
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Polyarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0

Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 10 (50.00%)	4 / 14 (28.57%)	8 / 24 (33.33%)
occurrences (all)	5	5	11
Dehydration			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	1	3	0
Hyperglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	3
Hypocalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	2
Hypomagnesaemia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 14 (7.14%)	2 / 24 (8.33%)
occurrences (all)	2	1	2
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)

occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	3 / 24 (12.50%)
occurrences (all)	0	2	6
Hypouricaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Tetany			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial translocation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Candida infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Cystitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Gastroenteritis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Lip infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Oral herpes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			

subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	3 / 10 (30.00%)	1 / 14 (7.14%)	2 / 24 (8.33%)
occurrences (all)	4	1	3

Non-serious adverse events	Cibisatamab QW CRC with OB	Cibisatamab Q3W CRC with OB	Cibisatamab Bile Duct
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	14 / 14 (100.00%)	2 / 2 (100.00%)
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Deep vein thrombosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Flushing			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	5 / 14 (35.71%)	0 / 2 (0.00%)
occurrences (all)	0	7	0
Phlebitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 10 (40.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	4	1	0
Chest discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	4 / 10 (40.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	7	1	0
Face oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 10 (20.00%)	3 / 14 (21.43%)	0 / 2 (0.00%)
occurrences (all)	4	3	0
Feeling hot			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)

occurrences (all)	0	1	0
Inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	5 / 10 (50.00%)	5 / 14 (35.71%)	1 / 2 (50.00%)
occurrences (all)	10	7	2
Swelling face			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Delirium			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mental disorder			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Scrotal oedema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Uterine pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	5 / 10 (50.00%)	12 / 14 (85.71%)	2 / 2 (100.00%)
occurrences (all)	5	23	2
Limb injury			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rib fracture			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Blood albumin decreased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Blood calcium decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 10 (20.00%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Blood iron decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Lymphocyte count decreased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Oxygen saturation decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Serum ferritin decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Blood cholesterol decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Congestive cardiovascular insufficiency			

subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Catarhh			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Dry throat			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Laryngeal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Pleural effusion			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Productive cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 10 (30.00%)	2 / 14 (14.29%)	1 / 2 (50.00%)
occurrences (all)	4	2	1
Bandaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 10 (20.00%)	4 / 14 (28.57%)	0 / 2 (0.00%)
occurrences (all)	2	4	0
Facial nerve disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Facial paralysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuralgia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Neurotoxicity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Dry eye			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Macular oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Tympanic membrane perforation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	3 / 10 (30.00%)	3 / 14 (21.43%)	1 / 2 (50.00%)
occurrences (all)	4	6	1
Abdominal pain lower			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Ascites			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Colitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 10 (10.00%)	6 / 14 (42.86%)	0 / 2 (0.00%)
occurrences (all)	1	8	0
Diarrhoea			
subjects affected / exposed	6 / 10 (60.00%)	6 / 14 (42.86%)	1 / 2 (50.00%)
occurrences (all)	8	11	1
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	1 / 2 (50.00%)
occurrences (all)	0	2	1
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lumbar hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	2 / 10 (20.00%)	8 / 14 (57.14%)	1 / 2 (50.00%)
occurrences (all)	2	9	1
Odynophagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	1 / 2 (50.00%)
occurrences (all)	0	3	1
Subileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Tongue oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 10 (20.00%)	6 / 14 (42.86%)	0 / 2 (0.00%)
occurrences (all)	2	7	0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nephropathy toxic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oliguria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Renal impairment			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatic function abnormal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	3 / 14 (21.43%)	0 / 2 (0.00%)
occurrences (all)	0	6	0
Hypertransaminasaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Ocular icterus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Petechiae			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	2 / 10 (20.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Rash macular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin exfoliation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	3 / 14 (21.43%)	1 / 2 (50.00%)
occurrences (all)	0	3	1
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0

Myalgia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Polyarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 10 (20.00%)	6 / 14 (42.86%)	0 / 2 (0.00%)
occurrences (all)	3	6	0
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	3 / 10 (30.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Hypocalcaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	2 / 14 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Hypouricaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tetany			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bacterial translocation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lip infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 10 (0.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Oral candidiasis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 14 (7.14%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	2 / 10 (20.00%)	0 / 14 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Cibisatamab Breast	Cibisatamab Lung	Cibisatamab Pancreatic
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	4 / 4 (100.00%)	8 / 8 (100.00%)
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vasculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	2 / 4 (50.00%)	5 / 8 (62.50%)
occurrences (all)	1	2	5
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	4 / 8 (50.00%)
occurrences (all)	0	0	10
Face oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	2
Feeling hot			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 2 (100.00%)	0 / 4 (0.00%)	6 / 8 (75.00%)
occurrences (all)	3	0	14
Swelling face			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mental disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Uterine pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed	1 / 2 (50.00%)	4 / 4 (100.00%)	4 / 8 (50.00%)
occurrences (all)	7	14	5
Limb injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Blood calcium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)

occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Platelet count increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Blood cholesterol decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Congestive cardiovascular insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catarhh			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Dry throat			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphonia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Laryngeal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Bandaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disturbance in Attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)

occurrences (all)	1	1	2
Facial nerve disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Macular oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Abdominal pain lower			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	5
Diarrhoea			
subjects affected / exposed	1 / 2 (50.00%)	3 / 4 (75.00%)	3 / 8 (37.50%)

occurrences (all)	3	8	6
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lumbar hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	2 / 4 (50.00%)	3 / 8 (37.50%)
occurrences (all)	2	4	3
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Subileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tongue oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 2 (100.00%)	1 / 4 (25.00%)	3 / 8 (37.50%)
occurrences (all)	2	1	4
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nephropathy toxic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hepatic function abnormal			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypertransaminasaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Ocular icterus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palmar erythema			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Petechiae			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pain in Extremity			
subjects affected / exposed	1 / 2 (50.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Polyarthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	4 / 8 (50.00%)
occurrences (all)	0	2	4
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 4 (75.00%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 4 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hypouricaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Metabolic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tetany			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial translocation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 4 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Periodontitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)

occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 4 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2

Non-serious adverse events	Cibisatamab Other	Cibisatamab Alone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	6 / 6 (100.00%)	
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Phlebitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vasculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Venous thrombosis limb			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	5	0	
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Face oedema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Feeling hot			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Infusion site extravasation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Localised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Xerosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Mental disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Prostatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Scrotal oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Uterine pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			
subjects affected / exposed	5 / 6 (83.33%)	1 / 6 (16.67%)	
occurrences (all)	6	1	
Limb injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Post-traumatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rib fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin abrasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Wound			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Blood albumin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	

occurrences (all)	1	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood calcium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood cholesterol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Blood iron decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
C-reactive protein increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Lymphocyte count decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oxygen saturation decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Platelet count increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Serum ferritin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urine output decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood cholesterol decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cardiac failure			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Congestive cardiovascular insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Catarhh			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Dry throat			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Laryngeal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pulmonary oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Throat irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Bandaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Disturbance in Attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Facial nerve disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Facial paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	

occurrences (all)	1	0	
Neurotoxicity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Peripheral motor neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Taste disorder			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dry eye			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Eye haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eyelid function disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Macular oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tympanic membrane perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	

occurrences (all)	1	0	
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Diarrhoea			
subjects affected / exposed	4 / 6 (66.67%)	0 / 6 (0.00%)	
occurrences (all)	8	0	
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Enteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Glossodynia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	

occurrences (all)	1	0	
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lumbar hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	3 / 6 (50.00%)	1 / 6 (16.67%)	
occurrences (all)	3	1	
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oral dysaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Proctalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Subileus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Tongue oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	

occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nephropathy toxic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nocturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oliguria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary retention			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hepatic function abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ocular icterus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	

occurrences (all)	1	0	
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperkeratosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Palmar erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Petechiae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pruritis			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Rash			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Rash macular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin exfoliation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Arthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pain in Extremity			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Polyarthritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hypouricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Metabolic acidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tetany			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gout			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypercholesterolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bacterial translocation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Herpes virus infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lip infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	

Oropharyngeal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Periodontitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 August 2017	Revised eligibility criteria
18 April 2018	Discontinued enrollment; updated eligibility criteria.
18 May 2019	Amended secondary PFS objective; added mandatory 8-hour observation period after RO6958688 under specified circumstances; amended AE reporting period.

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.

Results are from an abbreviated CSR and do not include pharmacodynamic data.

Notes: