Clinical trial results:
An Open-Label, Multicenter, Dose-Escalation Phase Ib Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Therapeutic Activity of Selicrelumab (CD40 Agonist) in Combination with Atezolizumab (Anti-PDL1) in Patients with Locally Advanced and/or Metastatic Solid Tumors.

Summary

EudraCT number	2014-002835-32
Trial protocol	ES FR
Global end of trial date	07 November 2019

Results information

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

Trial information

Trial identification

Sponsor protocol code	BP29392

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02304393
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	07 November 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	07 November 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The purpose of this trial was to assess the safety, pharmacokinetics, pharmacodynamics, and activity of selicrelumab administered in combination with atezolizumab (ATZ) in participants with metastatic or locally advanced solid tumors.

Protection of trial subjects:

All participants were required to sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 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: 14
Country: Number of subjects enrolled	Denmark: 16
Country: Number of subjects enrolled	France: 53
Country: Number of subjects enrolled	Netherlands: 35
Country: Number of subjects enrolled	Spain: 20
Country: Number of subjects enrolled	United States: 2
Worldwide total number of subjects	140
EEA total number of subjects	124

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)	94
From 65 to 84 years	46
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Adult participants with metastatic or locally advanced solid tumors not amenable to standard therapies.

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	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)

Arm description:

Participants received a fixed-dose of 16 mg intravenous (IV) selicrelumab in combination with 1200 mg of IV atezolizumab (ATZ).

Arm type	Experimental
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received IV selicrelumab at a fixed dose of 16 mg on Cycle 1 Day 1.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab Q3W starting Cycle 2 Day 1, or escalating doses of atezolizumab Q4W up to 1200 mg.

Arm title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)

Arm description:

Participants received 1 mg of subcutaneous (SC) selicrelumab in combination with 1200 mg of IV ATZ.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab Q3W starting Cycle 2 Day 1.

Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection

Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received escalating doses of SC selicrelumab on Cycle 1 Day 1.

Arm title	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)

Arm description:

Participants received 2 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Arm type	Experimental
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received escalating doses of SC selicrelumab on Cycle 1 Day 1.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab Q3W starting Cycle 2 Day 1.

Arm title	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)

Arm description:

Participants received 16 mg of SC selicrelumab in combination with 1200 mg of ATZ.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab Q3W starting Cycle 2 Day 1.

Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received escalating doses of SC selicrelumab on Cycle 1 Day 1.

Arm title	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)

Arm description:

Participants received 32 mg of SC selicrelumab in combination with 1200 mg of ATZ.

Arm type	Experimental
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details: Participants received escalating doses of SC selicrelumab on Cycle 1 Day 1.	
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	RO5541267
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Participants received 1200 mg of IV atezolizumab Q3W starting Cycle 2 Day 1.	
Arm title	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Arm description: Participants received up to 9 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	RO5541267
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.	
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Participants received escalating doses of SC selicrelumab on Cycle 1 Day 2.	
Arm title	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)
Arm description: Participants received 12-21 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Arm type	Experimental
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Participants received escalating doses of SC selicrelumab on Cycle 1 Day 2.	
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	RO5541267
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.	
Arm title	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)
Arm description: Participants received 28-36 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Arm type	Experimental

Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received escalating doses of SC selicrelumab on Cycle 1 Day 2.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.

Arm title	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)

Arm description:

Participants received 48-64 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Arm type	Experimental
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received escalating doses of SC selicrelumab on Cycle 1 Day 2.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.

Arm title	Part 2 (SC): Small + Large Bowel Carcinoma

Arm description:

Participants with small and large bowel carcinoma received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.

Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 16 mg of SC selicrelumab for 4 administrations starting Cycle 1, then Q12W thereafter.

Arm title	Part 2 (SC): HNSCC

Arm description:

Participants with head and neck squamous cell carcinoma (HNSCC) received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Arm type	Experimental
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 16 mg of SC selicrelumab for 4 administrations starting Cycle 1, then Q12W thereafter.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.

Arm title	Part 2 (SC): NSCLC

Arm description:

Participants with non-small cell lung cancer received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Arm type	Experimental
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 16 mg of SC selicrelumab for 4 administrations starting Cycle 1, then Q12W thereafter.

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

Dosage and administration details:

Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.

Number of subjects in period 1	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)
Started	6	5	7
Completed	6	5	7

Number of subjects in period 1	Part 1A Cohort 3:	Part 1A Cohort 4:	Part 1B: ATZ 1200

	ATZ 1200 mg + Selicrelumab 16 mg (SC)	ATZ 1200 mg + Selicrelumab 32 mg (SC)	mg + Selicrelumab 1-9 mg (SC)
Started	8	4	31
Completed	8	4	31

Number of subjects in period 1	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Started	16	9	9
Completed	16	9	9

Number of subjects in period 1	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC
Started	12	19	14
Completed	12	19	14

Baseline characteristics

Reporting groups	
Reporting group title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)
Reporting group description:	
Participants received a fixed-dose of 16 mg intravenous (IV) selicrelumab in combination with 1200 mg of IV atezolizumab (ATZ).	
Reporting group title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)
Reporting group description:	
Participants received 1 mg of subcutaneous (SC) selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)
Reporting group description:	
Participants received 2 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Reporting group description:	
Participants received 16 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)
Reporting group description:	
Participants received 32 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Reporting group description:	
Participants received up to 9 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)
Reporting group description:	
Participants received 12-21 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)
Reporting group description:	
Participants received 28-36 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Reporting group description:	
Participants received 48-64 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 2 (SC): Small + Large Bowel Carcinoma
Reporting group description:	
Participants with small and large bowel carcinoma received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 2 (SC): HNSCC
Reporting group description:	
Participants with head and neck squamous cell carcinoma (HNSCC) received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 2 (SC): NSCLC
Reporting group description:	
Participants with non-small cell lung cancer received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	

Reporting group values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)
Number of subjects	6	5	7

Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3	3	6
From 65-84 years	3	2	1
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	60.7	54.0	48.1
standard deviation	± 13.6	± 20.1	± 13.9
Gender Categorical Units: Subjects			
Female	2	3	5
Male	4	2	2
Race Units: Subjects			
Asian	0	0	2
White	6	2	4
Unknown	0	3	1
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	1	3
Not Stated	0	2	2
Unknown	0	2	2

Reporting group values	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Number of subjects	8	4	31
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	3	24
From 65-84 years	3	1	7
85 years and over	0	0	0

Age Continuous Units: years			
arithmetic mean	54.5	52.0	56.7
standard deviation	± 13.0	± 15.5	± 9.8
Gender Categorical Units: Subjects			
Female	2	2	19
Male	6	2	12
Race Units: Subjects			
Asian	0	0	1
White	5	3	14
Unknown	3	1	16
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	5
Not Hispanic or Latino	5	3	8
Not Stated	3	1	10
Unknown	0	0	8

Reporting group values	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Number of subjects	16	9	9
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	12	4	6
From 65-84 years	4	5	3
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	53.4	59.1	56.4
standard deviation	± 15.8	± 16.8	± 12.2
Gender Categorical Units: Subjects			
Female	7	6	6
Male	9	3	3
Race Units: Subjects			
Asian	1	1	0
White	8	3	6
Unknown	7	5	3
Ethnicity Units: Subjects			
Hispanic or Latino	2	0	0

Not Hispanic or Latino	6	4	6
Not Stated	4	2	0
Unknown	4	3	3

Reporting group values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC
Number of subjects	12	19	14
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	12	10
From 65-84 years	6	7	4
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	63.1	60.9	60.4
standard deviation	± 8.3	± 11.1	± 8.5
Gender Categorical Units: Subjects			
Female	6	6	6
Male	6	13	8
Race Units: Subjects			
Asian	0	0	0
White	7	7	1
Unknown	5	12	13
Ethnicity Units: Subjects			
Hispanic or Latino	2	0	0
Not Hispanic or Latino	5	7	1
Not Stated	2	6	9
Unknown	3	6	4

Reporting group values	Total		
Number of subjects	140		
Age Categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	94		
From 65-84 years	46		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical			
Units: Subjects			
Female	70		
Male	70		
Race			
Units: Subjects			
Asian	5		
White	66		
Unknown	69		
Ethnicity			
Units: Subjects			
Hispanic or Latino	9		
Not Hispanic or Latino	55		
Not Stated	41		
Unknown	35		

End points reporting groups

Reporting group title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)
Reporting group description:	
Participants received a fixed-dose of 16 mg intravenous (IV) selicrelumab in combination with 1200 mg of IV atezolizumab (ATZ).	
Reporting group title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)
Reporting group description:	
Participants received 1 mg of subcutaneous (SC) selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)
Reporting group description:	
Participants received 2 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Reporting group description:	
Participants received 16 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)
Reporting group description:	
Participants received 32 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Reporting group description:	
Participants received up to 9 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)
Reporting group description:	
Participants received 12-21 mg of SC selicrelumab in combination with 1200 mg of ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)
Reporting group description:	
Participants received 28-36 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Reporting group description:	
Participants received 48-64 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 2 (SC): Small + Large Bowel Carcinoma
Reporting group description:	
Participants with small and large bowel carcinoma received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 2 (SC): HNSCC
Reporting group description:	
Participants with head and neck squamous cell carcinoma (HNSCC) received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Reporting group title	Part 2 (SC): NSCLC
Reporting group description:	
Participants with non-small cell lung cancer received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.	
Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 1 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.	
Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 2 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 4 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 6 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 9 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 12 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 16 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 21 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 28 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 32 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 36 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 48 mg

Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 64 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

Primary: Number of Participants with Adverse Events (AEs) and Serious AEs

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

End point description:

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

End point type	Primary

End point timeframe:

Up to approximately 59 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 1 study.

End point values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	7	8
Units: Number of Participants				
number (not applicable)				
AEs	5	5	7	8
SAEs	2	2	5	1

End point values	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	31	16	9
Units: Number of Participants				
number (not applicable)				
AEs	4	31	16	9
SAEs	1	9	5	3

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	12	19	14
Units: Number of Participants				
number (not applicable)				
AEs	9	12	19	14
SAEs	4	4	4	6

Statistical analyses

No statistical analyses for this end point

Primary: Part IB: Maximum Tolerated Dose (MTD) of Selicrelumab

End point title	Part IB: Maximum Tolerated Dose (MTD) of Selicrelumab[2][3]

End point description:

The MTD was not reached and is not reported.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 - Cycle 2 Day 2 (cycle length = 21 days)

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 1 study.

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31[4]	16[5]	9[6]	9[7]
Units: mg				
number (not applicable)	9999	9999	9999	9999

Notes:

[4] - 9999 = The MTD was not reached and is not reported.

[5] - 9999 = The MTD was not reached and is not reported.

[6] - 999 = The MTD was not reached and is not reported.

[7] - 999 = The MTD was not reached and is not reported.

Statistical analyses

No statistical analyses for this end point

Primary: Part IB: Recommended Part II Dose of Selicrelumab

End point title	Part IB: Recommended Part II Dose of Selicrelumab[8][9]

End point description:

The dose for Part II was to be defined based on the MTD established in Part IB. Since the MTD was not reached, the recommended dose of selicrelumab was based on available safety and tolerability data. The values reported are the maximum dose provided in each arm.

End point type	Primary

End point timeframe:

Cycle 1 Day 1 - Cycle 2 Day 2 (cycle length = 21 days)

Notes:

[8] - 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 1 study.

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	16	9	9
Units: mg				
number (not applicable)	9	21	36	64

Statistical analyses

No statistical analyses for this end point

Primary: Part IB: Number of Participants with Dose-Limiting Toxicities (DLTs)

End point title	Part IB: Number of Participants with Dose-Limiting Toxicities (DLTs)[10][11]

End point description:

A DLT was defined as a protocol-defined toxicity related to selicrelumab and/or atezolizumab that occurred during the DLT-assessment window.

End point type	Primary

End point timeframe:

Day 1 of Cycles 2, 3, 4, and 5

Notes:

[10] - 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 1 study.

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	16	9	9
Units: Number of Participants	2	1	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Percentage of Participants With Best Overall Response (BOR), as Determined by Investigator Using Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

End point title	Part II: Percentage of Participants With Best Overall Response (BOR), as Determined by Investigator Using Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1[12][13]

End point description:

BOR was defined as a best response of complete response (CR), partial response (PR), stable disease (SD), or progressive disease (PD).

End point type	Primary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[12] - 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 1 study.

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	19	14	
Units: Percentage of Participants				
number (confidence interval 95%)				
CR	0.00 (0.00 to 0.00)	5.3 (0.00 to 15.30)	0 (0.00 to 0.00)	
PR	0 (0.00 to 0.00)	10.5 (0.00 to 24.33)	0 (0.00 to 0.00)	
SD	0 (0.00 to 0.00)	26.3 (6.52 to 46.12)	57.1 (31.22 to 83.07)	
PD	100.0 (100.00 to 100.00)	42.1 (19.90 to 64.31)	35.7 (10.61 to 60.81)	

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Progression-Free Survival (PFS), as Determined by Investigator Using RECIST Version 1.1

End point title	Part II: Progression-Free Survival (PFS), as Determined by Investigator Using RECIST Version 1.1[14][15]

End point description:

PFS was defined as the time from the first study treatment to the first occurrence of disease progression or death, whichever occurred first.

End point type	Primary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 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 1 study.

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	19	14	
Units: Days				
median (confidence interval 95%)	38.0 (37.0 to 39.0)	48.0 (37.0 to 122.0)	81.0 (38.0 to 127.0)	

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Duration of Objective Response (DOR), as Determined by Investigator Using RECIST v1.1

End point title	Part II: Duration of Objective Response (DOR), as Determined by Investigator Using RECIST v1.1[16][17]

End point description:

DOR was defined as the time from the first occurrence of a documented objective response to the time of relapse or death from any cause, whichever occurred first.

End point type	Primary

End point timeframe:

First occurence of response to relapse or death from any cause, whichever occurred first (up to 58 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 1 study.

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[18]	19	14[19]	
Units: Days				
median (confidence interval 95%)	9999 (9999 to 9999)	483.0 (232.0 to 533.0)	9999 (9999 to 9999)	

Notes:

[18] - 9999 = Data missing or unevaluable.

[19] - 9999 = Data missing or unevaluable.

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Percentage of Participants With Disease Control, as Determined by Investigator Using RECIST Version 1.1

End point title	Part II: Percentage of Participants With Disease Control, as Determined by Investigator Using RECIST Version 1.1[20][21]

End point description:

Disease control rate (DCR) was defined as CR, PR, or SD lasting at least 6 weeks (per RECIST v1.1)

End point type	Primary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 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 1 study.

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12[22]	19	14	
Units: Percentage of Participants				
number (not applicable)	9999	31.6	35.7	

Notes:

[22] - 9999 = Data missing or unevaluable

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Overall Survival (OS)

End point title	Part II: Overall Survival (OS)[23][24]

End point description:

OS was defined as the time from first study treatment to death. Overall survival was not summarized for this study.

End point type	Primary

End point timeframe:

Baseline to death from any cause (up to approximately 58 months)

Notes:

[23] - 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 1 study.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[25]	0[26]	0[27]	
Units: N/A				
number (not applicable)				

Notes:

[25] - Overall survival was not summarized for this study.

[26] - Overall survival was not summarized for this study.

[27] - Overall survival was not summarized for this study.

Statistical analyses

No statistical analyses for this end point

Primary: Part II: PFS, as Determined by Investigator Using Unidimensional irRC

End point title	Part II: PFS, as Determined by Investigator Using Unidimensional irRC[28][29]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Primary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[28] - 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 1 study.

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[30]	0[31]	0[32]	
Units: N/A				
number (not applicable)				

Notes:

[30] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[31] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[32] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Percentage of Participants With BOR, as Determined by Investigator Using Unidimensional Immune-Related Response Criteria (irRC)

End point title	Part II: Percentage of Participants With BOR, as Determined by Investigator Using Unidimensional Immune-Related Response Criteria (irRC)[33][34]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Primary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[33] - 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 1 study.

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[35]	0[36]	0[37]	
Units: N/A				
number (not applicable)				

Notes:

[35] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[36] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[37] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Percentage of Participants With Disease Control, as Determined by Investigator Using Unidimensional irRC

End point title	Part II: Percentage of Participants With Disease Control, as Determined by Investigator Using Unidimensional irRC[38][39]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Primary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[38] - 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 1 study.

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[40]	0[41]	0[42]	
Units: N/A				
number (not applicable)				

Notes:

[40] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[41] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[42] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Primary: Part II: DOR, as Determined by Investigator Using Unidimensional irRC

End point title	Part II: DOR, as Determined by Investigator Using Unidimensional irRC[43][44]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Primary

End point timeframe:

Baseline to progressive disease or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[43] - 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 1 study.

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[45]	0[46]	0[47]	
Units: N/A				
number (not applicable)				

Notes:

[45] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[46] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[47] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration Time Curve (AUC) of Selicrelumab (Single SC Dose)

End point title	Area Under the Concentration Time Curve (AUC) of Selicrelumab (Single SC Dose)

End point description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

End point type	Secondary

End point timeframe:

Cycle 1 (cycle = 21 days)

End point values	Pharmacokinetic (PK) Analysis Population - 1 mg	Pharmacokinetic (PK) Analysis Population - 2 mg	Pharmacokinetic (PK) Analysis Population - 4 mg	Pharmacokinetic (PK) Analysis Population - 6 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	11	10	4
Units: ug*h/mL				
geometric mean (geometric coefficient of variation)	3.45 (± 30)	4.06 (± 49)	4.80 (± 71)	15.37 (± 29)

End point values	Pharmacokinetic (PK) Analysis Population - 9 mg	Pharmacokinetic (PK) Analysis Population - 12 mg	Pharmacokinetic (PK) Analysis Population - 16 mg	Pharmacokinetic (PK) Analysis Population - 21 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	56	7
Units: ug*h/mL				
geometric mean (geometric coefficient of variation)	10.15 (± 63)	16.18 (± 59)	36.76 (± 47)	33.98 (± 51)

End point values	Pharmacokinetic (PK) Analysis Population - 28 mg	Pharmacokinetic (PK) Analysis Population - 32 mg	Pharmacokinetic (PK) Analysis Population - 36 mg	Pharmacokinetic (PK) Analysis Population - 48 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	4	5	4
Units: ug*h/mL				
geometric mean (geometric coefficient of variation)	70.74 (± 29)	85.20 (± 46)	86.01 (± 10)	111.63 (± 25)

End point values	Pharmacokinetic (PK) Analysis Population - 64 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: ug*h/mL				
geometric mean (geometric coefficient of variation)	178.55 (± 28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Serum Concentration (Cmax) of Selicrelumab (Single SC Dose)

End point title	Maximum Serum Concentration (Cmax) of Selicrelumab (Single SC Dose)

End point description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

End point type	Secondary

End point timeframe:

Cycle 1 (cycle = 21 days)

End point values	Pharmacokinetic (PK) Analysis Population - 1 mg	Pharmacokinetic (PK) Analysis Population - 2 mg	Pharmacokinetic (PK) Analysis Population - 4 mg	Pharmacokinetic (PK) Analysis Population - 6 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	11	10	4
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0004 (± 80)	0.0010 (± 100)	0.0026 (± 107)	0.0014 (± 100)

End point values	Pharmacokinetic (PK) Analysis Population - 9 mg	Pharmacokinetic (PK) Analysis Population - 12 mg	Pharmacokinetic (PK) Analysis Population - 16 mg	Pharmacokinetic (PK) Analysis Population - 21 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	56	7
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0046 (± 126)	0.0105 (± 50)	0.0159 (± 75)	0.0097 (± 105)

End point values	Pharmacokinetic (PK) Analysis Population - 28 mg	Pharmacokinetic (PK) Analysis Population - 32 mg	Pharmacokinetic (PK) Analysis Population - 36 mg	Pharmacokinetic (PK) Analysis Population - 48 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	4	5	4
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0173 (± 59)	0.0172 (± 89)	0.0204 (± 59)	0.0089 (± 104)

End point values	Pharmacokinetic (PK) Analysis Population - 64 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0382 (± 80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Cmax (Tmax) of Selicrelumab (Single SC Dose)

End point title	Time to Cmax (Tmax) of Selicrelumab (Single SC Dose)

End point description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

End point type	Secondary

End point timeframe:

Cycle 1 (cycle = 21 days)

End point values	Pharmacokinetic (PK) Analysis Population - 1 mg	Pharmacokinetic (PK) Analysis Population - 2 mg	Pharmacokinetic (PK) Analysis Population - 4 mg	Pharmacokinetic (PK) Analysis Population - 6 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	11	10	4
Units: Hours				
median (full range (min-max))	72.12 (47.83 to 501.92)	481.20 (68.58 to 523.23)	71.57 (24.07 to 486.55)	71.19 (69.75 to 481.33)

End point values	Pharmacokinetic (PK) Analysis Population - 9 mg	Pharmacokinetic (PK) Analysis Population - 12 mg	Pharmacokinetic (PK) Analysis Population - 16 mg	Pharmacokinetic (PK) Analysis Population - 21 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	56	7
Units: Hours				
median (full range (min-max))	48.07 (46.32 to 71.25)	478.80 (46.50 to 480.47)	144.12 (46.67 to 484.38)	48.53 (46.13 to 484.32)

End point values	Pharmacokinetic (PK) Analysis Population - 28 mg	Pharmacokinetic (PK) Analysis Population - 32 mg	Pharmacokinetic (PK) Analysis Population - 36 mg	Pharmacokinetic (PK) Analysis Population - 48 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	4	5	4
Units: Hours				
median (full range (min-max))	70.85 (48.93 to 480.15)	163.12 (69.17 to 360.67)	163.50 (47.58 to 452.08)	120.91 (70.23 to 482.33)

End point values	Pharmacokinetic (PK) Analysis Population - 64 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: Hours				
median (full range (min-max))	167.42 (71.75 to 505.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Serum Concentration Under Steady-State (Cmin) of Selicrelumab (Single SC Dose)

End point title	Minimum Serum Concentration Under Steady-State (Cmin) of Selicrelumab (Single SC Dose)

End point description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

End point type	Secondary

End point timeframe:

Cycle 1 (cycle = 21 days)

End point values	Pharmacokinetic (PK) Analysis Population - 1 mg	Pharmacokinetic (PK) Analysis Population - 2 mg	Pharmacokinetic (PK) Analysis Population - 4 mg	Pharmacokinetic (PK) Analysis Population - 6 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	11	10	4
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0004 (± 80)	0.0010 (± 100)	0.0033 (± 127)	0.0014 (± 100)

End point values	Pharmacokinetic (PK) Analysis Population - 9 mg	Pharmacokinetic (PK) Analysis Population - 12 mg	Pharmacokinetic (PK) Analysis Population - 16 mg	Pharmacokinetic (PK) Analysis Population - 21 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	56	7
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0046 (± 126)	0.0105 (± 50)	0.0165 (± 73)	0.0097 (± 105)

End point values	Pharmacokinetic (PK) Analysis Population - 28 mg	Pharmacokinetic (PK) Analysis Population - 32 mg	Pharmacokinetic (PK) Analysis Population - 36 mg	Pharmacokinetic (PK) Analysis Population - 48 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	4	5	4
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0173 (± 59)	0.0172 (± 89)	0.0204 (± 59)	0.0089 (± 104)

End point values	Pharmacokinetic (PK) Analysis Population - 64 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	5			

Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.0382 (± 80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part IA: Cmax of Atezolizumab

End point title	Part IA: Cmax of Atezolizumab[48]

End point description:

The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1a, therefore other arms were excluded.

End point values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[49]	0[50]	0[51]	0[52]
Units: N/A				
number (not applicable)				

Notes:

[49] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[50] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[51] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[52] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point values	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)			
Subject group type	Reporting group			
Number of subjects analysed	0[53]			
Units: N/A				
number (not applicable)				

Notes:

[53] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IA: Cmin of Atezolizumab

End point title	Part IA: Cmin of Atezolizumab[54]

End point description:

The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1a, therefore other arms were excluded.

End point values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[55]	0[56]	0[57]	0[58]
Units: N/A				
number (not applicable)				

Notes:

[55] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[56] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[57] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[58] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point values	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)			
Subject group type	Reporting group			
Number of subjects analysed	0[59]			
Units: N/A				
number (not applicable)				

Notes:

[59] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC of SC Selicrelumab (Repeated SC Dose)

End point title	AUC of SC Selicrelumab (Repeated SC Dose)

End point description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

End point type	Secondary

End point timeframe:

Cycles 1-7 (cycle = 21 days)

End point values	Pharmacokinetic (PK) Analysis Population - 16 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	56			
Units: ug*h/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n= 56)	36.76 (± 47)			
Cycle 2 (n= 30)	55.65 (± 41)			
Cycle 3 (n=15)	58.95 (± 41)			
Cycle 4 (n=10)	79.92 (± 37)			
Cycle 5 (n= 8)	73.14 (± 38)			
Cycle 6 (n=6)	71.85 (± 43)			
Cycle 7 (n=5)	58.18 (± 28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of SC Selicrelumab (Repeated SC Dose)

End point title	Cmax of SC Selicrelumab (Repeated SC Dose)

End point description:

PK data from participants who received at least one dose of selicrelumab were included in the treatment's PK analysis. Participants that significantly violated exclusion criteria, deviated significantly from the protocol, or that had unavailable or incomplete data were excluded from the analysis.

End point type	Secondary

End point timeframe:

Cycles 1-7 (cycle = 21 days)

End point values	Pharmacokinetic (PK) Analysis Population - 16 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	56			
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=56)	0.0159 (± 75)			
Cycle 2 (n=30)	0.0233 (± 45)			
Cycle 3 (n=15)	0.0274 (± 42)			
Cycle 4 (n=10)	0.0106 (± 52)			
Cycle 5 (n=8)	0.0105 (± 57)			

Cycle 6 (n=6)	0.0104 (± 50)			
Cycle 7 (n=5)	0.0095 (± 50)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Cmax of Atezolizumab

End point title	Part IB: Cmax of Atezolizumab[60]

End point description:

The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[61]	0[62]	0[63]	0[64]
Units: N/A				
number (not applicable)				

Notes:

[61] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[62] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.
.

[63] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[64] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Cmin of Atezolizumab

End point title	Part IB: Cmin of Atezolizumab[65]

End point description:

The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

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

Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[66]	0[67]	0[68]	0[69]
Units: N/A				
number (not applicable)				

Notes:

[66] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[67] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[68] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[69] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Cmax of Atezolizumab

End point title	Part II: Cmax of Atezolizumab[70]

End point description:

The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

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

Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[71]	0[72]	0[73]	
Units: N/A				
number (not applicable)				

Notes:

[71] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[72] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[73] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Cmin of Atezolizumab

End point title	Part II: Cmin of Atezolizumab[74]

End point description:

The pharmacokinetics for atezolizumab were not derived and hence are not reported.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[75]	0[76]	0[77]	
Units: N/A				
number (not applicable)				

Notes:

[75] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[76] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

[77] - The pharmacokinetics for atezolizumab were not derived and hence are not reported.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Percentage of Participants With BOR, as Determined by Investigator Using Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1

End point title	Part IB: Percentage of Participants With BOR, as Determined by Investigator Using Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1[78]

End point description:

BOR was defined as a best response of complete response (CR), partial response (PR), stable disease (SD), or progressive disease (PD).

End point type	Secondary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurs first (up to approximately 58 months)

Notes:

[78] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	16	9	9
Units: Percentage of Participants				
number (confidence interval 95%)				
CR	0 (0.00 to 0.00)	0 (0.00 to 0.00)	0 (0.00 to 0.00)	0 (0.00 to 0.00)

PR	9.7 (0.00 to 20.08)	6.3 (0.00 to 18.11)	33.3 (2.54 to 64.13)	0 (0.00 to 0.00)
SD	45.2 (27.64 to 62.68)	25.0 (3.78 to 46.22)	44.4 (11.98 to 76.91)	77.8 (50.62 to 100.00)
PD	29.0 (13.05 to 45.01)	56.3 (31.94 to 80.56)	22.2 (0.00 to 49.38)	22.2 (0.00 to 49.38)

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Percentage of Participants With Disease Control, as Determined by Investigator Using RECIST Version 1.1

End point title	Part IB: Percentage of Participants With Disease Control, as Determined by Investigator Using RECIST Version 1.1[79]

End point description:

Disease control rate (DCR) was defined as CR, PR, or SD lasting at least 6 weeks (per RECIST v1.1)

End point type	Secondary

End point timeframe:

Baseline to disease progression or death to any cause, whichever occurred first (up to approximately 58 months)

Notes:

[79] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	16	9	9
Units: Percentage of Participants				
number (not applicable)	38.7	18.8	55.6	33.3

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: DOR, as Determined by Investigator Using RECIST Version 1.1

End point title	Part IB: DOR, as Determined by Investigator Using RECIST Version 1.1[80]

End point description:

DOR was defined as the time from the first occurrence of a documented objective response to the time of relapse or death from any cause, whichever occurred first.

End point type	Secondary

End point timeframe:

First occurrence of response to relapse or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	16[81]	9	9[82]
Units: Days				
median (confidence interval 95%)	230.0 (212.0 to 570.0)	676.0 (0 to 9999)	340.0 (81.0 to 534.0)	9999 (9999 to 9999)

Notes:

[81] - 9999 = Data missing or unevaluable

[82] - 9999 = Data missing or unevaluable

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: PFS, as Determined by Investigator Using RECIST Version 1.1

End point title	Part IB: PFS, as Determined by Investigator Using RECIST Version 1.1[83]

End point description:

PFS was defined as the time from the first study treatment to the first occurrence of disease progression or death, whichever occurred first.

End point type	Secondary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[83] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.
No formal statistical analyses were planned for this phase 1 study.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	16	9	9
Units: Days				
median (confidence interval 95%)	82.0 (42.0 to 178.0)	37.0 (35.0 to 78.0)	119.0 (94.0 to 165.0)	82.0 (79.0 to 121.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Part IA: Levels of Circulating Ki67 T cells Assessed by Immunophenotyping by Flow Cytometry

End point title	Part IA: Levels of Circulating Ki67 T cells Assessed by Immunophenotyping by Flow Cytometry[84]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1a, therefore other arms were excluded.

End point values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[85]	0[86]	0[87]	0[88]
Units: N/A				
number (not applicable)				

Notes:

[85] - No pharmacodynamic results are reported due to premature study discontinuation.

[86] - No pharmacodynamic results are reported due to premature study discontinuation.

[87] - No pharmacodynamic results are reported due to premature study discontinuation.

[88] - No pharmacodynamic results are reported due to premature study discontinuation.

End point values	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)			
Subject group type	Reporting group			
Number of subjects analysed	0[89]			
Units: N/A				
number (not applicable)				

Notes:

[89] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Levels of Circulating Ki67 T Cells Assessed by Immunophenotyping by Flow Cytometry

End point title	Part IB: Levels of Circulating Ki67 T Cells Assessed by Immunophenotyping by Flow Cytometry[90]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[91]	0[92]	0[93]	0[94]
Units: N/A				
number (not applicable)				

Notes:

[91] - No pharmacodynamic results are reported due to premature study discontinuation.

[92] - No pharmacodynamic results are reported due to premature study discontinuation.

[93] - No pharmacodynamic results are reported due to premature study discontinuation.

[94] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Levels of Circulating Ki67 T Cells Assessed by Immunophenotyping by Flow Cytometry

End point title	Part II: Levels of Circulating Ki67 T Cells Assessed by Immunophenotyping by Flow Cytometry[95]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[95] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[96]	0[97]	0[98]	
Units: N/A				
number (not applicable)				

Notes:

[96] - No pharmacodynamic results are reported due to premature study discontinuation.

[97] - No pharmacodynamic results are reported due to premature study discontinuation.

[98] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IA: Levels of Cluster of Differentiation 8 (CD8+) Cells Tumor-Infiltration Assessed by Immunophenotyping by Flow Cytometry

End point title	Part IA: Levels of Cluster of Differentiation 8 (CD8+) Cells Tumor-Infiltration Assessed by Immunophenotyping by Flow Cytometry[99]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[99] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1a, therefore other arms were excluded.

End point values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[100]	0[101]	0[102]	0[103]
Units: N/A				
number (not applicable)				

Notes:

[100] - No pharmacodynamic results are reported due to premature study discontinuation.

[101] - No pharmacodynamic results are reported due to premature study discontinuation.

[102] - No pharmacodynamic results are reported due to premature study discontinuation.

[103] - No pharmacodynamic results are reported due to premature study discontinuation.

End point values	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)			
Subject group type	Reporting group			
Number of subjects analysed	0[104]			
Units: N/A				
number (not applicable)				

Notes:

[104] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Levels of CD8+ Cells Tumor-Infiltration Assessed by Immunophenotyping by Flow Cytometry

End point title	Part IB: Levels of CD8+ Cells Tumor-Infiltration Assessed by Immunophenotyping by Flow Cytometry[105]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[105] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[106]	0[107]	0[108]	0[109]
Units: N/A				
number (not applicable)				

Notes:

[106] - No pharmacodynamic results are reported due to premature study discontinuation.

[107] - No pharmacodynamic results are reported due to premature study discontinuation.

[108] - No pharmacodynamic results are reported due to premature study discontinuation.

[109] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IA: Levels of Programmed Death Ligand 1 (PD-L1) Expression on Both Tumor and Immune-Infiltrating Cells Assessed by Immunophenotyping by Flow Cytometry

End point title	Part IA: Levels of Programmed Death Ligand 1 (PD-L1) Expression on Both Tumor and Immune-Infiltrating Cells Assessed by Immunophenotyping by Flow Cytometry[110]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[110] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1a, therefore other arms were excluded.

End point values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[111]	0[112]	0[113]	0[114]
Units: N/A				
number (not applicable)				

Notes:

[111] - No pharmacodynamic results are reported due to premature study discontinuation.

[112] - No pharmacodynamic results are reported due to premature study discontinuation.

[113] - No pharmacodynamic results are reported due to premature study discontinuation.

[114] - No pharmacodynamic results are reported due to premature study discontinuation.

End point values	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)			
Subject group type	Reporting group			
Number of subjects analysed	0[115]			
Units: N/A				
number (not applicable)				

Notes:

[115] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Levels of PD-L1 Expression on Both Tumor and Immune-Infiltrating Cells Assessed by Immunophenotyping by Flow Cytometry

End point title	Part IB: Levels of PD-L1 Expression on Both Tumor and Immune-Infiltrating Cells Assessed by Immunophenotyping by Flow Cytometry[116]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

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

Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[117]	0[118]	0[119]	0[120]
Units: N/A				
number (not applicable)				

Notes:

[117] - No pharmacodynamic results are reported due to premature study discontinuation.

[118] - No pharmacodynamic results are reported due to premature study discontinuation.

[119] - No pharmacodynamic results are reported due to premature study discontinuation.

[120] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Levels of PD-L1 Expression on Both Tumor and Immune-

Infiltrating Cells Assessed by Immunophenotyping by Flow Cytometry

End point title	Part II: Levels of PD-L1 Expression on Both Tumor and Immune-Infiltrating Cells Assessed by Immunophenotyping by Flow Cytometry[121]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[121] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[122]	0[123]	0[124]	
Units: N/A				
number (not applicable)				

Notes:

[122] - No pharmacodynamic results are reported due to premature study discontinuation.

[123] - No pharmacodynamic results are reported due to premature study discontinuation.

[124] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Levels of CD8+ Cells Tumor-Infiltration Assessed by Immunophenotyping by Flow Cytometry

End point title	Part II: Levels of CD8+ Cells Tumor-Infiltration Assessed by Immunophenotyping by Flow Cytometry[125]

End point description:

No pharmacodynamic results are reported due to premature study discontinuation.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[125] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[126]	0[127]	0[128]	
Units: N/A				
number (not applicable)				

Notes:

[126] - No pharmacodynamic results are reported due to premature study discontinuation.

[127] - No pharmacodynamic results are reported due to premature study discontinuation.

[128] - No pharmacodynamic results are reported due to premature study discontinuation.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IA: Percentage of Participants with Incidence of Anti-Drug Antibodies (ADA) Responses to Selicrelumab

End point title	Part IA: Percentage of Participants with Incidence of Anti-Drug Antibodies (ADA) Responses to Selicrelumab[129]

End point description:

Samples from participants treated with selicrelumab and atezolizumab were analyzed for ADAs.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[129] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1a, therefore other arms were excluded.

End point values	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	7	8
Units: Percentage of Participants				
number (not applicable)				
Treatment-induced ADAs	0	0	14.3	0
Treatment-enhanced ADAs	0	0	0	0

End point values	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Percentage of Participants				
number (not applicable)				
Treatment-induced ADAs	0			
Treatment-enhanced ADAs	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Percentage of Participants with Incidence of ADA Responses to Selicrelumab

End point title	Part IB: Percentage of Participants with Incidence of ADA Responses to Selicrelumab[130]

End point description:

Samples from participants treated with selicrelumab and atezolizumab were analyzed for ADAs.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[130] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	16	9	9
Units: Percentage of participants				
number (not applicable)				
Treatment-induced ADA	6.5	12.5	11.1	0
Treatment-enhanced ADA	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Percentage of Participants with Incidence of ADA Responses to Selicrelumab

End point title	Part II: Percentage of Participants with Incidence of ADA Responses to Selicrelumab[131]

End point description:

Samples from participants treated with selicrelumab and atezolizumab were analyzed for ADAs.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[131] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 2, therefore other arms were excluded.

End point values	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): HNSCC	Part 2 (SC): NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	19	14	
Units: Percentage of Participants				
number (not applicable)				
Treatment-induced ADA	0	0	0	
Treatment-enhanced ADA	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: Percentage of Participants With BOR, as Determined by Investigator Using Unidimensional Immune-Related Response Criteria (irRC)

End point title	Part IB: Percentage of Participants With BOR, as Determined by Investigator Using Unidimensional Immune-Related Response Criteria (irRC)[132]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Secondary

End point timeframe:

Baseline to disease progression or death from any cause, whichever occurred first (up to approximately 58 months)

Notes:

[132] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[133]	0[134]	0[135]	0[136]
Units: Percentage of Participants				
number (not applicable)				

Notes:

[133] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[134] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[135] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[136] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Part Ib: Duration of Objective Response, as Determined by Investigator Using Unidimensional irRC

End point title	Part Ib: Duration of Objective Response, as Determined by Investigator Using Unidimensional irRC[137]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[137] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[138]	0[139]	0[140]	0[141]
Units: N/A				
number (not applicable)				

Notes:

[138] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[139] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[140] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[141] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Part Ib: Percentage of Participants With Disease Control, as Determined by Investigator Using Unidimensional irRC

End point title	Part Ib: Percentage of Participants With Disease Control, as Determined by Investigator Using Unidimensional irRC[142]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[142] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[143]	0[144]	0[145]	0[146]
Units: N/A				
number (not applicable)				

Notes:

[143] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[144] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[145] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[146] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Secondary: Part IB: PFS, as Determined by Investigator Using Unidimensional irRC

End point title	Part IB: PFS, as Determined by Investigator Using Unidimensional irRC[147]

End point description:

Unidimensional irRC endpoints were not analyzed for this study due to early termination.

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[147] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This end point was specific to part 1b, therefore other arms were excluded.

End point values	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[148]	0[149]	0[150]	0[151]
Units: N/A				
number (not applicable)				

Notes:

[148] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[149] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[150] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

[151] - Unidimensional irRC endpoints were not analyzed for this study due to early termination.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Up to 58 months

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)

Reporting group description:

Participants received 1 mg of subcutaneous (SC) selicrelumab in combination with 1200 mg of IV ATZ.

Reporting group title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)

Reporting group description:

Participants received a fixed-dose of 16 mg intravenous (IV) selicrelumab in combination with 1200 mg of IV atezolizumab (ATZ).

Reporting group title	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)

Reporting group description:

Participants received 16 mg of SC selicrelumab in combination with 1200 mg of ATZ.

Reporting group title	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)

Reporting group description:

Participants received 2 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Reporting group title	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)

Reporting group description:

Participants received 32 mg of SC selicrelumab in combination with 1200 mg of ATZ.

Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)

Reporting group description:

Participants received up to 9 mg of SC selicrelumab in combination with 1200 mg of ATZ.

Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)

Reporting group description:

Participants received 12-21 mg of SC selicrelumab in combination with 1200 mg of ATZ.

Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)

Reporting group description:

Participants received 28-36 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)

Reporting group description:

Participants received 48-64 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Reporting group title	Part 2 (SC): Small + Large Bowel Carcinoma

Reporting group description:

Participants with small and large bowel carcinoma received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Reporting group title	Part 2 (SC): NSCLC

Reporting group description:

Participants with non-small cell lung cancer received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Reporting group title	Part 2 (SC): HNSCC

Reporting group description:

Participants with head and neck squamous cell carcinoma (HNSCC) received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ.

Serious adverse events	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	2 / 6 (33.33%)	1 / 8 (12.50%)
number of deaths (all causes)	5	3	7
number of deaths resulting from adverse events			
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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)			
Metastases to heart			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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			
Injection site reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (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			
Femoral neck fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Investigations			
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (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			
Left ventricular dysfunction			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (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
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Immune-mediated pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	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
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	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
Pancytopenia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	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
Nervous system disorders			
Optic neuritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	1 / 6 (16.67%)	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

Urinary tract obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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			
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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			
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Encephalitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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
Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (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	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	1 / 4 (25.00%)	9 / 31 (29.03%)
number of deaths (all causes)	5	2	21
number of deaths resulting from adverse events			
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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)			
Metastases to heart			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tumour pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
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	0 / 7 (0.00%)	1 / 4 (25.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (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
Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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			
Left ventricular dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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			
Optic neuritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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 pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 16 (31.25%)	3 / 9 (33.33%)	4 / 9 (44.44%)
number of deaths (all causes)	10	4	5
number of deaths resulting from adverse events			
Vascular disorders			

Haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to heart			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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			
Injection site reaction			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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			
Femoral neck fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (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
Infusion related reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (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
Transaminases increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Left ventricular dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune-mediated pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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			
Optic neuritis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (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

Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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			
Back pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (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
Spinal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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			
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (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

Serious adverse events	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): NSCLC	Part 2 (SC): HNSCC
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 12 (33.33%)	6 / 14 (42.86%)	4 / 19 (21.05%)
number of deaths (all causes)	8	7	11
number of deaths resulting from adverse events			
Vascular disorders			
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to heart			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Left ventricular dysfunction			

subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune-mediated pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (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
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Optic neuritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (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
Infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 14 (14.29%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 16 mg (IV)	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	5 / 6 (83.33%)	8 / 8 (100.00%)
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)

occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Intermittent claudication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tumour associated fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Axillary pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Catheter site inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
General physical health deterioration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hernia pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Injection site inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Swelling face			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cyst			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 5 (40.00%)	2 / 6 (33.33%)	2 / 8 (25.00%)
occurrences (all)	4	3	2
Injection site atrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	4 / 5 (80.00%)	0 / 6 (0.00%)	7 / 8 (87.50%)
occurrences (all)	4	0	7
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	6 / 8 (75.00%)
occurrences (all)	1	1	9

Psychiatric disorders			
Anhedonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Arthropod bite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eschar			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	3 / 6 (50.00%)	1 / 8 (12.50%)
occurrences (all)	0	3	1
Injection related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pubis fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stoma site extravasation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 5 (40.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 5 (40.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Blood alkaline phosphatase increase			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)

occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			

disorders			
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	4 / 8 (50.00%)
occurrences (all)	0	2	4
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Laryngeal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 5 (40.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	3
Respiratory disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	4 / 8 (50.00%)
occurrences (all)	1	0	4
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphatic insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Cervicobrachial syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 5 (20.00%)	2 / 6 (33.33%)	1 / 8 (12.50%)
occurrences (all)	3	2	1
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pruritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Maculopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Xerophthalmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0

Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 5 (40.00%)	0 / 6 (0.00%)	3 / 8 (37.50%)
occurrences (all)	2	0	3
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	3 / 5 (60.00%)	1 / 6 (16.67%)	4 / 8 (50.00%)
occurrences (all)	5	1	4
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	4
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	2	4
Pancreatitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1

Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Erythema multiforme			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail toxicity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Decubitis ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	2

Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Product issues			
Device dislocation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	3	0	1
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Tendon pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cushing's syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hyperthyroidism			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)

occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	2	2
Iron deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Orchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Sepsis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Lip infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Intervertebral discitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eyelid infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Catheter site abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Bronchitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Viral rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Non-serious adverse events	Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC)	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	4 / 4 (100.00%)	31 / 31 (100.00%)
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Intermittent claudication			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Infected neoplasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 4 (0.00%)	9 / 31 (29.03%)
occurrences (all)	2	0	14
Axillary pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hernia pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hyperthermia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	3
Influenza like illness			
subjects affected / exposed	2 / 7 (28.57%)	0 / 4 (0.00%)	4 / 31 (12.90%)
occurrences (all)	4	0	6
Injection site inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Mucosal dryness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Swelling face			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 31 (9.68%)
occurrences (all)	0	0	4
Cyst			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 7 (42.86%)	2 / 4 (50.00%)	9 / 31 (29.03%)
occurrences (all)	3	2	10
Injection site atrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	7 / 7 (100.00%)	4 / 4 (100.00%)	28 / 31 (90.32%)
occurrences (all)	7	4	28
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 7 (42.86%)	1 / 4 (25.00%)	8 / 31 (25.81%)
occurrences (all)	4	1	12
Psychiatric disorders			
Anhedonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0

Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Anxiety disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Eschar			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	5
Injection related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Pubis fracture			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Stoma site extravasation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	2 / 31 (6.45%)
occurrences (all)	2	1	2
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	2 / 31 (6.45%)
occurrences (all)	2	1	2
Blood alkaline phosphatase increase			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	2 / 7 (28.57%)	0 / 4 (0.00%)	2 / 31 (6.45%)

occurrences (all)	2	0	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	4 / 31 (12.90%)
occurrences (all)	1	0	5
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	3 / 31 (9.68%)
occurrences (all)	1	1	3
Hepatic enzyme increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Neutrophil count increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Weight increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Serum ferritin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	5 / 31 (16.13%)
occurrences (all)	2	1	5
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	2 / 7 (28.57%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Cough			
subjects affected / exposed	1 / 7 (14.29%)	2 / 4 (50.00%)	6 / 31 (19.35%)
occurrences (all)	1	2	6
Respiratory disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 7 (42.86%)	1 / 4 (25.00%)	4 / 31 (12.90%)
occurrences (all)	5	1	6
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lymphatic insufficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	4 / 31 (12.90%)
occurrences (all)	1	1	4
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cervicobrachial syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)

occurrences (all)	0	0	3
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Loss of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	1	0	3
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)

occurrences (all)	0	0	0

Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Eye pruritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Maculopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Xerophthalmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	3 / 31 (9.68%)

occurrences (all)	1	0	6
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	8 / 31 (25.81%)
occurrences (all)	0	0	9
Diarrhoea			
subjects affected / exposed	3 / 7 (42.86%)	0 / 4 (0.00%)	6 / 31 (19.35%)
occurrences (all)	4	0	12
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	1 / 4 (25.00%)	15 / 31 (48.39%)

occurrences (all)	1	1	20
Pancreatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 31 (9.68%)
occurrences (all)	0	0	3
Vomiting			
subjects affected / exposed	2 / 7 (28.57%)	1 / 4 (25.00%)	6 / 31 (19.35%)
occurrences (all)	2	1	8
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	4 / 31 (12.90%)
occurrences (all)	0	0	4
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)

occurrences (all)	0	0	1
Erythema multiforme			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	2
Macule			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nail toxicity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Decubitis ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	4 / 31 (12.90%)
occurrences (all)	0	0	4
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 31 (9.68%)
occurrences (all)	0	0	3
Rash maculo-papular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Skin burning sensation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			

subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin swelling			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	2 / 31 (6.45%)
occurrences (all)	0	1	2
Back pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	5 / 31 (16.13%)
occurrences (all)	2	0	7
Flank pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	3
Groin pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)

occurrences (all)	0	0	2
Musculoskeletal disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	5 / 31 (16.13%)
occurrences (all)	3	0	6
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 4 (25.00%)	1 / 31 (3.23%)
occurrences (all)	0	1	1
Pain in extremity			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	1	0	3
Tendon pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 31 (9.68%)
occurrences (all)	0	0	3
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Decreased appetite			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	5 / 31 (16.13%)
occurrences (all)	1	0	5
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Gout			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	4 / 31 (12.90%)
occurrences (all)	1	0	4
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Hypochloraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	3 / 31 (9.68%)
occurrences (all)	1	0	3

Hypomagnesaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	1	0	2
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Orchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)

occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Intervertebral discitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	1	0	1
Oral fungal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)

occurrences (all)	0	0	0
Eyelid infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Catheter site abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)

occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1B: ATZ 1200 mg + Selicrelumab 12-21 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	9 / 9 (100.00%)	9 / 9 (100.00%)
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intermittent claudication			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Tumour pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 16 (31.25%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	5	0	1
Axillary pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	3 / 16 (18.75%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	4	0	0
General physical health deterioration			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hernia pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Influenza like illness			
subjects affected / exposed	2 / 16 (12.50%)	2 / 9 (22.22%)	0 / 9 (0.00%)
occurrences (all)	2	6	0
Injection site inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 16 (6.25%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 16 (0.00%)	2 / 9 (22.22%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 16 (18.75%)	4 / 9 (44.44%)	7 / 9 (77.78%)
occurrences (all)	3	8	11

Injection site atrophy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	13 / 16 (81.25%)	8 / 9 (88.89%)	7 / 9 (77.78%)
occurrences (all)	14	8	7
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	4 / 16 (25.00%)	4 / 9 (44.44%)	2 / 9 (22.22%)
occurrences (all)	5	8	2
Psychiatric disorders			
Anhedonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Anxiety disorder			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Vaginal discharge			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Vulvovaginal pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eschar			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	2 / 9 (22.22%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Infusion related reaction			
subjects affected / exposed	2 / 16 (12.50%)	0 / 9 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	3
Injection related reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pubis fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	0	0	0
Stoma site extravasation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 16 (31.25%)	1 / 9 (11.11%)	1 / 9 (11.11%)
occurrences (all)	6	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 16 (37.50%)	1 / 9 (11.11%)	1 / 9 (11.11%)
occurrences (all)	7	1	1
Blood alkaline phosphatase increase			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 16 (12.50%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 16 (12.50%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	4	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	1	0	0
Blood urea increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 16 (25.00%)	1 / 9 (11.11%)	2 / 9 (22.22%)
occurrences (all)	4	1	2
Hepatic enzyme increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 16 (0.00%)	2 / 9 (22.22%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Weight increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Platelet count decreased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	2 / 16 (12.50%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	1	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 16 (0.00%)	3 / 9 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	3	1
Respiratory disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 16 (18.75%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	5	1	0
Leukopenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			

subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Lymphatic insufficiency			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Neutropenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Cervicobrachial syndrome			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	1 / 16 (6.25%)	3 / 9 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	3	1
Dysaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 16 (18.75%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	3	2	0
Hypoaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 9 (22.22%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Somnolence			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye pruritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	0	0	0
Maculopathy			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	2 / 16 (12.50%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Xerophthalmia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	3 / 16 (18.75%)	1 / 9 (11.11%)	3 / 9 (33.33%)
occurrences (all)	3	1	3
Ascites			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	4 / 16 (25.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Diarrhoea			
subjects affected / exposed	4 / 16 (25.00%)	3 / 9 (33.33%)	2 / 9 (22.22%)
occurrences (all)	8	4	6

Dyspepsia			
subjects affected / exposed	1 / 16 (6.25%)	2 / 9 (22.22%)	2 / 9 (22.22%)
occurrences (all)	2	2	2
Dysphagia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 9 (11.11%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
Flatulence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 16 (25.00%)	3 / 9 (33.33%)	2 / 9 (22.22%)
occurrences (all)	7	8	3
Pancreatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 16 (6.25%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Stomatitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Toothache			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	3 / 16 (18.75%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Colitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	3 / 16 (18.75%)	3 / 9 (33.33%)	1 / 9 (11.11%)
occurrences (all)	3	7	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Urinary tract pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	0	0	0

Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Cholestasis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Hepatic pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 16 (6.25%)	2 / 9 (22.22%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Erythema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	1	0	0
Nail toxicity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Decubitis ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	5 / 16 (31.25%)	3 / 9 (33.33%)	0 / 9 (0.00%)
occurrences (all)	5	3	0
Rash			
subjects affected / exposed	1 / 16 (6.25%)	2 / 9 (22.22%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Rash maculo-papular			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Skin burning sensation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vitiligo			

subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 16 (12.50%)	3 / 9 (33.33%)	0 / 9 (0.00%)
occurrences (all)	2	4	0
Back pain			
subjects affected / exposed	1 / 16 (6.25%)	2 / 9 (22.22%)	2 / 9 (22.22%)
occurrences (all)	1	3	2
Flank pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	2 / 16 (12.50%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Muscular weakness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	3 / 16 (18.75%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	2	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	3 / 9 (33.33%)	1 / 9 (11.11%)
occurrences (all)	0	3	1
Tendon pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cushing's syndrome			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Decreased appetite			
subjects affected / exposed	2 / 16 (12.50%)	4 / 9 (44.44%)	1 / 9 (11.11%)
occurrences (all)	2	8	1
Dehydration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Hypercalcaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 9 (22.22%)	0 / 9 (0.00%)
occurrences (all)	0	2	0

Iron deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Orchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	2 / 16 (12.50%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lip infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	0	0	0
Intervertebral discitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 9 (22.22%)	1 / 9 (11.11%)
occurrences (all)	0	3	1
Infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pneumonia viral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Eyelid infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	4 / 9 (44.44%)	1 / 9 (11.11%)
occurrences (all)	0	6	1
Catheter site abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	1 / 9 (11.11%)
occurrences (all)	0	1	3
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2 (SC): Small + Large Bowel Carcinoma	Part 2 (SC): NSCLC	Part 2 (SC): HNSCC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	14 / 14 (100.00%)	19 / 19 (100.00%)

Vascular disorders			
Embolism			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	2 / 19 (10.53%)
occurrences (all)	1	1	3
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Intermittent claudication			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Lymphoedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Venous thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tumour pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)	9 / 14 (64.29%)	3 / 19 (15.79%)
occurrences (all)	1	12	5
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	3 / 14 (21.43%)	1 / 19 (5.26%)
occurrences (all)	0	3	1
General physical health deterioration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hernia pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperthermia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Injection site inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)

occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Oedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	3
Swelling face			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Catheter site pruritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	4 / 12 (33.33%)	1 / 14 (7.14%)	4 / 19 (21.05%)
occurrences (all)	5	1	4
Injection site atrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	11 / 12 (91.67%)	14 / 14 (100.00%)	17 / 19 (89.47%)
occurrences (all)	17	28	14
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)

occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	7 / 12 (58.33%)	7 / 14 (50.00%)	7 / 19 (36.84%)
occurrences (all)	9	10	15
Psychiatric disorders			
Anhedonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Anxiety disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Vaginal discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eschar			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	2 / 12 (16.67%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Injection related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pubis fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Stoma site extravasation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Stoma site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	2 / 12 (16.67%)	2 / 14 (14.29%)	3 / 19 (15.79%)
occurrences (all)	3	2	3
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 12 (25.00%)	1 / 14 (7.14%)	5 / 19 (26.32%)
occurrences (all)	4	1	8
Blood alkaline phosphatase increase			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 14 (14.29%)	1 / 19 (5.26%)
occurrences (all)	0	3	2
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 14 (14.29%)	2 / 19 (10.53%)
occurrences (all)	0	2	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 14 (14.29%)	2 / 19 (10.53%)
occurrences (all)	1	4	2
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Blood urea increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Gamma-glutamyltransferase			

increased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 14 (14.29%)	3 / 19 (15.79%)
occurrences (all)	1	2	3
Hepatic enzyme increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	1	1	2
Lipase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Serum ferritin increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 12 (16.67%)	2 / 14 (14.29%)	4 / 19 (21.05%)
occurrences (all)	2	2	4
Dyspnoea exertional			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Pneumothorax			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	3 / 12 (25.00%)	3 / 14 (21.43%)	6 / 19 (31.58%)
occurrences (all)	3	3	6
Respiratory disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 12 (16.67%)	4 / 14 (28.57%)	7 / 19 (36.84%)
occurrences (all)	4	4	11
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphatic insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 14 (21.43%)	4 / 19 (21.05%)
occurrences (all)	0	4	4

Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Thrombocytopenia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 14 (14.29%)	0 / 19 (0.00%)
occurrences (all)	1	3	0
Nervous system disorders			
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	2 / 12 (16.67%)	3 / 14 (21.43%)	2 / 19 (10.53%)
occurrences (all)	2	3	2
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Loss of consciousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)

occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Taste disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Eye pruritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Maculopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Xerophthalmia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Ascites			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	2 / 12 (16.67%)	3 / 14 (21.43%)	5 / 19 (26.32%)
occurrences (all)	2	3	6
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	2 / 19 (10.53%)
occurrences (all)	0	1	3
Dyspepsia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 14 (14.29%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)

occurrences (all)	0	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Intestinal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Intra-abdominal fluid collection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 12 (8.33%)	5 / 14 (35.71%)	2 / 19 (10.53%)
occurrences (all)	1	6	2
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	2 / 14 (14.29%)	0 / 19 (0.00%)

occurrences (all)	0	4	0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Vomiting			
subjects affected / exposed	1 / 12 (8.33%)	4 / 14 (28.57%)	3 / 19 (15.79%)
occurrences (all)	1	4	3
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Hepatic pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Onychoclasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Macule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nail toxicity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Decubitis ulcer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)

occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 12 (8.33%)	3 / 14 (21.43%)	1 / 19 (5.26%)
occurrences (all)	1	4	1
Rash			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)

occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	2 / 14 (14.29%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Flank pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 14 (0.00%)	2 / 19 (10.53%)
occurrences (all)	3	0	2
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 14 (14.29%)	2 / 19 (10.53%)
occurrences (all)	0	2	3
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)

occurrences (all)	0	0	0

Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Cushing's syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	2 / 12 (16.67%)	5 / 14 (35.71%)	3 / 19 (15.79%)
occurrences (all)	2	6	3
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	3 / 19 (15.79%)
occurrences (all)	0	1	3
Hyperglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 14 (21.43%)	3 / 19 (15.79%)

occurrences (all)	0	4	7
Hypernatraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	2 / 19 (10.53%)
occurrences (all)	0	1	3
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	4 / 14 (28.57%)	4 / 19 (21.05%)
occurrences (all)	0	7	8
Iron deficiency			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Oral herpes			

subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Orchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	3
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Lip infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Intervertebral discitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eyelid infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Subcutaneous abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Upper respiratory tract infection			

subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	1 / 12 (8.33%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	1	2	1
Catheter site abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	3 / 14 (21.43%)	0 / 19 (0.00%)
occurrences (all)	0	4	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 January 2015	Clarified enrollment rules for Part IA cohort 2 and Part IB.
21 April 2015	Added a subcohort to the study.
09 December 2015	Changed selicrelumab administration to SC only; added safety run-in phase and dose escalation to Part IA; implemented additional safety measures.
11 December 2016	Modifications to selicrelumab administration routes; amended contraception requirements for male and female participants.
06 September 2017	Change to study design (merged parts II and III); updates to primary and secondary objectives.
19 December 2017	Additional safety guidelines and information; updated eligibility criteria.
16 November 2018	Update to selicrelumab route of administration in parts Ib and II; update to eligibility criteria.

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.

Sponsor discontinued development of selicrelumab in combination with atezolizumab due to observed limited clinical benefit. These results are abbreviated and focus on detailed safety results, limited efficacy summaries and pharmacokinetic data.

Notes: