

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:	

Noces

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

Canada: 14
Denmark: 16
France: 53
Netherlands: 35
Spain: 20
United States: 2
140
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). Experimental Arm type Investigational medicinal product name Selicrelumab Investigational medicinal product code RO7009789 Other name 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. Experimental Arm type Atezolizumab Investigational medicinal product name Investigational medicinal product code RO5541267 Other name Solution for infusion Pharmaceutical forms 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 selicrel	umab 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 atez	zolizumab Q3W starting Cycle 2 Day 1.
Arm title	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Arm description:	<u> </u>
	elumab in combination with 1200 mg of ATZ.
Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	, reconzumas
Other name	RO5541267
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	Third verious use
Participants received 1200 mg of IV atez	volizumah O3W starting Cycle 2 Day 1.
Investigational medicinal product name	Selicrelumab
Investigational medicinal product code	- Constitution
Other name	RO7009789
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	Journal of the Control of the Contro
Participants received escalating doses of	SC selicrelumah on Cycle 1 Day 1
Arm title	Part 1A Cohort 4: ATZ 1200 mg + Selicrelumab 32 mg (SC)
Arm description:	olumph in combination with 1200 mg of AT7
_	elumab in combination with 1200 mg of ATZ.
Arm type	Experimental
Investigational medicinal product cade	Selicrelumab
Investigational medicinal product code	DOZ000700
	RO7009789
Other name Pharmaceutical forms	Solution for injection

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Dosage and administration details:	CC adianaharah an Cala 1 Day 1
Participants received escalating doses of	
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	DOEE 44267
Other name	R05541267
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 1200 mg of IV atez	
Arm title	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Arm description:	
Participants received up to 9 mg of SC s	elicrelumab 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:	1
<u> </u>	zolizumab 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:	- Caseataneous use
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:	
·	licrelumab 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
Decade and administration details:	
Dosage and administration details:	
_	zolizumab on Cycle 1 Day 1, and Q3W thereafter.
_	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)
Participants received 1200 mg of IV atez	
Participants received 1200 mg of IV atez Arm title Arm description:	
Participants received 1200 mg of IV atez Arm title Arm description:	Part 1B: ATZ 1200 mg + Selicrelumab 28-36 mg (SC)

Selicrelumab
RO7009789
Solution for injection
Subcutaneous use
SC selicrelumab on Cycle 1 Day 2.
Atezolizumab
RO5541267
Solution for infusion
Intravenous use
zolizumab on Cycle 1 Day 1, and Q3W thereafter.
Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
1
licrelumab in combination with 1200 mg of IV ATZ.
Experimental
Selicrelumab
RO7009789
Solution for injection
Subcutaneous use
SC selicrelumab on Cycle 1 Day 2.
Atezolizumab
Atezolizumab
Atezolizumab RO5541267 Solution for infusion
Atezolizumab RO5541267
Atezolizumab RO5541267 Solution for infusion Intravenous use
Atezolizumab RO5541267 Solution for infusion
Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter.
Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter.
Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Part 2 (SC): Small + Large Bowel Carcinoma carcinoma received 16 mg of SC selicrelumab in combination
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Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Part 2 (SC): Small + Large Bowel Carcinoma carcinoma received 16 mg of SC selicrelumab in combination Experimental Atezolizumab RO5541267 Solution for infusion Intravenous use
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Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Part 2 (SC): Small + Large Bowel Carcinoma carcinoma received 16 mg of SC selicrelumab in combination Experimental Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Selicrelumab RO7009789
Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Part 2 (SC): Small + Large Bowel Carcinoma carcinoma received 16 mg of SC selicrelumab in combination Experimental Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Selicrelumab RO7009789 Solution for injection
Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Part 2 (SC): Small + Large Bowel Carcinoma carcinoma received 16 mg of SC selicrelumab in combination Experimental Atezolizumab RO5541267 Solution for infusion Intravenous use colizumab on Cycle 1 Day 1, and Q3W thereafter. Selicrelumab RO7009789

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

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	Arm title	Part 2 (SC): HNSCC
combination with 1200 mg of IV ATZ. Arm type	Arm description:	
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 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 details: Participants received 16 mg of SC selicrelumab for 4 administrations starting Cycle 1, then Q12W thereafter. Investigational medicinal product name RO7009789 Pharmaceutical forms Solution for injection Routes of administration details: Participants received 16 mg of SC selicrelumab for 4 administrations starting Cycle 1, then Q12W thereafter. Investigational medicinal product name RO5541267 Pharmaceutical forms Solution for infusion Routes of administration details: Posage and administration Intravenous use Dosage and administration Intravenous use		us cell carcinoma (HNSCC) received 16 mg of SC selicrelumab in
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 type 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 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 details:	Arm type	Experimental
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Dosage and administration details: Participants received 16 mg of SC selicrelumab for 4 administrations starting Cycle 1, then Q12W thereafter. Investigational medicinal product name	Pharmaceutical forms	Solution for injection
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 name RO5541267 Pharmaceutical forms Solution for infusion Routes of administration Intravenous use Dosage and administration Intravenous use	Routes of administration	Subcutaneous use
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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 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 name Atezolizumab Investigational medicinal product code Other name RO5541267 Pharmaceutical forms Solution for infusion Routes of administration Intravenous use Dosage and administration Intravenous use	Investigational medicinal product name	Atezolizumab
Pharmaceutical forms Routes of administration 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 Investigational medicinal product code Other name RO7009789 Pharmaceutical forms Solution for injection Routes of administration Dosage and administration details: Participants received 16 mg of SC selicrelumab for 4 administrations starting Cycle 1, then Q12W thereafter. Investigational medicinal product code Other name RO5541267 Pharmaceutical forms Solution for infusion Routes of administration Intravenous use Dosage and administration Intravenous use	Investigational medicinal product code	
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 Intravenous use	Other name	RO5541267
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 Intravenous use	Pharmaceutical forms	Solution for infusion
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 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 Investigational medicinal product code Other name RO5541267 Pharmaceutical forms Solution for infusion Routes of administration Intravenous use Dosage and administration details:	Routes of administration	Intravenous use
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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	Participants received 1200 mg of IV atez	olizumab on Cycle 1 Day 1, and Q3W thereafter.
Participants with non-small cell lung cancer received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ. Arm type	Arm title	Part 2 (SC): NSCLC
Participants with non-small cell lung cancer received 16 mg of SC selicrelumab in combination with 1200 mg of IV ATZ. Arm type	Arm description:	
Arm type	Participants with non-small cell lung can	cer received 16 mg of SC selicrelumab in combination with 1200
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:		Experimental
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:	Investigational medicinal product name	Selicrelumab
Pharmaceutical forms Routes of administration 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 Routes of administration Intravenous use Dosage and administration details:	Investigational medicinal product code	
Routes of administration 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:	Other name	RO7009789
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 R05541267 Pharmaceutical forms Solution for infusion Routes of administration Intravenous use Dosage and administration details:	Pharmaceutical forms	Solution for injection
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:	Routes of administration	Subcutaneous use
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:	Dosage and administration details:	
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Other name RO5541267 Pharmaceutical forms Solution for infusion Routes of administration Intravenous use Dosage and administration details:	Investigational medicinal product name	Atezolizumab
Pharmaceutical forms Routes of administration Dosage and administration details: Solution for infusion Intravenous use	Investigational medicinal product code	
Routes of administration Intravenous use Dosage and administration details:	Other name	RO5541267
Dosage and administration details:	Pharmaceutical forms	Solution for infusion
-	Routes of administration	Intravenous use
Participants received 1200 mg of IV atezolizumab on Cycle 1 Day 1, and Q3W thereafter.	Dosage and administration details:	
	Participants received 1200 mg of IV atez	colizumab 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
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	1	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)	
Started	16	9	9
Completed	16	9	9

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

Baseline characteristics

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:
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 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:
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:
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 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:
Reporting group title Part 1A Cohort 2: ATZ 1200 mg + Selicrelumab 2 mg (SC) Reporting group description:
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:	Part 1A Cohort 1:	Part 1A Cohort 2:
	ATZ 1200 mg +	ATZ 1200 mg +	ATZ 1200 mg +
	Selicrelumab 16 mg	Selicrelumab 1 mg	Selicrelumab 2 mg
	(IV)	(SC)	(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

Т	ı	·
54.5	52.0	56.7
± 13.0	± 15.5	± 9.8
2	2	19
6	2	12
0	0	1
5	3	14
3	1	16
0	0	5
5	3	8
3	1	10
0	0	8
	± 13.0 2 6 0 5 3	± 13.0 ± 15.5 2 2 6 2 0 0 5 3 3 1 0 0 5 3 3 1

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

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 10 of IV atezolizumab (ATZ).	6 mg intravenous (IV) selicrelumab in combination with 1200 mg
Reporting group title	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1 mg (SC)
Reporting group description:	
Participants received 1 mg of subcutar	neous (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 selicr	elumab 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 selic	crelumab 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 selic	crelumab 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 s	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 s	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 s	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 bowe with 1200 mg of IV ATZ.	I carcinoma received 16 mg of SC selicrelumab in combination
Reporting group title	Part 2 (SC): HNSCC
Reporting group description:	
Participants with head and neck squam combination with 1200 mg of IV ATZ.	nous cell carcinoma (HNSCC) received 16 mg of SC selicrelumab ir
Reporting group title	Part 2 (SC): NSCLC
Reporting group description:	
Participants with non-small cell lung camg of IV ATZ.	ancer received 16 mg of SC selicrelumab in combination with 1200
Subject analysis set title	Pharmacokinetic (PK) Analysis Population - 1 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
treatment's PK analysis. Participants th	d at least one dose of selicrelumab were included in the nat significantly violated exclusion criteria, deviated significantly able 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 type	1 3 1

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
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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

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
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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

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)

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

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)	

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		Primary
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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

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 Determ	nined 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:	•

End point timerrame:

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

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
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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 i	not analyzed for this study due to early termination.

End point timeframe:

End point type

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.

Primary

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	e or death from any cause, whichever occurred first (up to approximat

Notes:

58 months)

[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	c (PK) Analysis	c (PK) Analysis		Pharmacokineti c (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	c (PK) Analysis	c (PK) Analysis	c (PK) Analysis	Pharmacokineti c (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	c (PK) Analysis	c (PK) Analysis	c (PK) Analysis	Pharmacokineti c (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	Pharmacokineti c (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)		

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	c (PK) Analysis		c (PK) Analysis	Pharmacokineti c (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	c (PK) Analysis	c (PK) Analysis	c (PK) Analysis	Pharmacokineti c (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	c (PK) Analysis	c (PK) Analysis	c (PK) Analysis	Pharmacokineti c (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	Pharmacokineti c (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)		

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	c (PK) Analysis		c (PK) Analysis	Pharmacokineti c (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	c (PK) Analysis		c (PK) Analysis	Pharmacokineti c (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	c (PK) Analysis	c (PK) Analysis	c (PK) Analysis	Pharmacokineti c (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	Pharmacokineti c (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)		

No statistical analyses for this end point

Secondary: 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:				

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

Cycle 1 (cycle = 21 days)			

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

End point title

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

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)	3: ATZ 1200 mg +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[49]	O ^[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)	3: ATZ 1200 mg +
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	O ^[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	O ^[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

End point title	AUC of SC Selicrelumab (Repeated SC Dose)
End point description:	
PK data from participants who r	received at least one dose of selicrelumab were included in the
treatment's PK analysis. Particip	
treatment's PK analysis. Particip	pants that significantly violated exclusion criteria, deviated significantly
treatment's PK analysis. Particip from the protocol, or that had u	pants that significantly violated exclusion criteria, deviated significantly inavailable or incomplete data were excluded from the analysis.

End point values	Pharmacokineti c (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)		

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)
Life politicule	Ciliax of 3C Selicielatilab (Repeated 3C 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	Pharmacokineti c (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)		

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]	O ^[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	O ^[66]	0 ^[67]	O ^[68]	O ^[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 v	vere 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	End point type	Secondary
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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	6.3 (0.00 to	33.3 (2.54 to	0 (0.00 to
	20.08)	18.11)	64.13)	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	56.3 (31.94 to	22.2 (0.00 to	22.2 (0.00 to
	45.01)	80.56)	49.38)	49.38)

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 a	as CR, PR, or SD lasting at least 6 weeks (per RECIST v1.1)	
End point type Secondary		
End point timoframo		

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)

[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 type
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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

	,	
	Part IA: Levels of Circulating Ki67 T cells Assessed by Immunophenotyping by Flow Cytometry ^[84]	
End point description:		
No pharmacodynamic results are reporte	d 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

immunophenotyping by How 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	ed due to premature study discontinuation.		
End point type	Secondary		
End point timeframe:			
Up to 58 months			

[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]	O ^[92]	O _[83]	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

initial option ocyping by them	cy cometa y
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 rep	ported 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	O ^[96]	O ^[97]	O ^[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:		
Un 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	Part 1A Cohort 1: ATZ 1200 mg + Selicrelumab 1	2: ATZ 1200 mg +	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab
	16 mg (IV)	mg (SC)	mg (SC)	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

initial option 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 repo	orted due to premature study discontinuation.					
End point type	Secondary					
End point timeframe:						

[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]	O ^[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

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.

Secondary

End point values	Part 1A Cohort 1: ATZ 1200	Part 1A Cohort 1: ATZ 1200	Part 1A Cohort 2: ATZ 1200	Part 1A Cohort 3: ATZ 1200
	mg +	mg +	mg +	mg +
	Selicrelumab 16 mg (IV)	Selicrelumab 1 mg (SC)	Selicrelumab 2 mg (SC)	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)			

[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

·	Part IB: Levels of PD-L1 Expression on Both Tumor and Immune-Infiltrating Cells Assessed by Immunophenotyping b 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)				

- [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	d 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.

	Part 1A Cohort 1: ATZ 1200	Part 1A Cohort 1: ATZ 1200	Part 1A Cohort 2: ATZ 1200	Part 1A Cohort 3: ATZ 1200
End point values	mg + Selicrelumab 16 mg (IV)	mg + Selicrelumab 1 mg (SC)	mg + Selicrelumab 2 mg (SC)	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 Responses to Selicrelumab ^[130]		
End point description:		
Samples from participants treated with	th 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

Part II: Percentage of Participants with Incidence of ADA Responses to Selicrelumab ^[131]			
End point description:			
Samples from participants treated wit	h selicrelumab and atezolizumab were analyzed for ADAs.		
End point type Secondary			
End point timeframe:			

Notes

Up to 58 months

[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.

Final maintains	C d
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			

[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)				

- [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

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:	,
	ocutaneous (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:	rate 1% conore 1. A12 1200 mg + Scherelands 10 mg (1V)
	e of 16 mg intravenous (IV) selicrelumab in combination with 1200 mg
Reporting group title	Part 1A Cohort 3: ATZ 1200 mg + Selicrelumab 16 mg (SC)
Reporting group description:	
Participants received 16 mg of So	C 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:	
	C selicrelumab in combination with 1200 mg of ATZ.
Reporting group title	Part 1B: ATZ 1200 mg + Selicrelumab 1-9 mg (SC)
Reporting group description:	
	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:	
	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:	, , , , , , , , , , , , , , , , , , , ,
	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:	
. 33	of SC selicrelumab in combination with 1200 mg of IV ATZ.
Reporting group title	Part 2 (SC): Small + Large Bowel Carcinoma
Reporting group description:	
	bowel carcinoma received 16 mg of SC selicrelumab in combination
Reporting group title	Part 2 (SC): NSCLC
Reporting group description:	
Participants with non-small cell lumg of IV ATZ.	ung cancer received 16 mg of SC selicrelumab in combination with 120
Reporting group title	Part 2 (SC): HNSCC
Reporting group description: Participants with head and neck s combination with 1200 mg of IV	squamous cell carcinoma (HNSCC) received 16 mg of SC selicrelumab i 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 number of deaths (all causes) number of deaths resulting from adverse events	2 / 5 (40.00%) 5	2 / 6 (33.33%) 3	1 / 8 (12.50%) 7
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			
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	Ì		
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
Нурохіа			
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			i
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

1			
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			
occurrences causally related to	0 / 0	0 / 0	0 / 0

treatment / all			
deaths causally related to treatment / all Transaminases increased	0 / 0	0 / 0	0 / 0
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			į į
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			i i
1	1	1	ı

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 (0 000/)	0 / 31 /0 000/)
	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	1		
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	I		İ
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			1
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 Infusion related reaction	0 / 0	0 / 0	0 / 0
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		I	
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

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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
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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	Ì

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 Subjects affected / exposed O / 12 (0.00%) O / 14 (0.00%) O / 19 (0.00%) O / 10 (0.00%)	1	1		
subjects affected / exposed occurrences causally related to treatment / all deaths causa	·	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all o/0 0/0		0 / 12 /0 000/)	0 / 14 /0 000/)	0 / 10 / 0 000/)
treatment / all deaths causally related to treatment / all o/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0 0/0				
Pyrexia Subjects affected / exposed O / 12 (0.00%) O / 14 (0.00%) 2 / 19 (10.53%) O / 14 (0.00%) O / 0 O	treatment / all	0 / 0	0 / 0	0 / 0
Subjects affected / exposed	· · · · · · · · · · · · · · · · · · ·	0/0	0 / 0	0 / 0
Occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all O/0 O/0 O/0 O/0	Pyrexia			
treatment / all deaths causally related to treatment / all	subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	2 / 19 (10.53%)
Treatment / all		0 / 0	0 / 0	1/3
Complications Femoral neck fracture Subjects affected / exposed 0 / 12 (0.00%) 1 / 14 (7.14%) 0 / 19 (0.00%) 0 / 1 0 / 0 0 / 0 0 / 1 0 / 0 0 /		0 / 0	0 / 0	0 / 0
subjects affected / exposed 0 / 12 (0.00%) 1 / 14 (7.14%) 0 / 19 (0.00%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 1 0 / 0 Infusion related reaction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Investigations Electrocardiogram repolarisation abnormality Electrocardiogram repolarisation abnormality 0 / 1 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) occurrences causally related to treatment / all 0 / 1 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 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 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 0 / 0 Transaminases increased subjects affected / exposed 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 19 (0.00%) occu	complications			
Occurrences causally related to treatment / all deaths causally related to treatment / all loads and the second of the second				
treatment / all deaths causally related to treatment / all	subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
treatment / ali		0 / 0	0 / 1	0 / 0
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 1 / 12 (8.33%) 0 / 14 (0.00%) 0 / 19 (0.00%) occurrences causally related to treatment / all 0 / 1 0 / 0 0 / 0 0 / 0 deaths causally related to treatment / all 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) occurrences causally related to treatment / all 0 / 0 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 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 0 / 0 deaths causally related to treatment / all 0 / 0 0 / 0	1	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0	Infusion related reaction			
treatment / all deaths causally related to treatment / all	subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
Treatment / all		0 / 0	0 / 0	0 / 0
Electrocardiogram repolarisation abnormality subjects affected / exposed	1	0/0	0 / 0	0 / 0
abnormality subjects affected / exposed	Investigations			
occurrences causally related to treatment / all 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%) 0 ccurrences causally related to treatment / all 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 / 0 Transaminases increased subjects affected / exposed 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 0 / 0 Cardiac disorders		<u> </u>		
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all O/0 Transaminases increased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all O/0 O/0 O/0 O/0 O/0 O/0 O/0 O	subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
treatment / all		0 / 1	0 / 0	0 / 0
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 0 / 0 Cardiac disorders Cardiac disorders 0 / 0 0 / 0 0 / 0 0 / 0		0/0	0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all	Hepatic enzyme increased			
treatment / all deaths causally related to treatment / all O / 0 O / 0 O / 0 O / 0 Transaminases increased subjects affected / exposed O / 12 (0.00%) Occurrences causally related to treatment / all deaths causally related to treatment / all O / 0 O / 0 O / 14 (0.00%) O / 0 O / 0 O / 0 Cardiac disorders	subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
treatment / all 0 / 0 0 / 0 0 / 0 Transaminases increased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 Cardiac disorders 0 / 0 0 / 0 0 / 0 0 / 0		0 / 0	0 / 0	0 / 0
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 0 / 0 deaths causally related to treatment / all 0 / 0 0 / 0 0 / 0 0 / 0 Cardiac disorders		0/0	0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 0 / 0 Cardiac disorders	Transaminases increased	I		İ
treatment / all deaths causally related to treatment / all Cardiac disorders	subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
deaths causally related to treatment / all 0 / 0 0 / 0 0 / 0 Cardiac disorders		0 / 0	0 / 0	0 / 0
		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			ĺ
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			i İ
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 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
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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

T			
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			l I
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)			
decarrences (un)	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
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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 / 0 000/)	0.76.70.0007	1 / 0 /12 500/)
	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
(4.17)	U	U	U
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 occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (aii)	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	7		
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 / 3 (0.00%)	0	0
Plaural offucion			
Pleural effusion subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
5			
Pneumothorax	0 / 5 / 0 6551	0 / 5 / 0 555 / 3	0.40.40.5553
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	1	I	1
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
To the discount of			
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 occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (aii)	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 / 0 000/)	0.46.40.000()	0 / 0 / 0 000/)
occurrences (all)	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 (0 000()	1 / 6 / 16 670/ \	0 / 9 /0 000/)
occurrences (all)	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
Coccarrences (un)	0	1	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)

astrointestinal 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	О
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
Haamarrhaida			
Haemorrhoids subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)			
occurrences (all)	0	1	0

occurrences (all)

Intestinal obstruction subjects affected / exposed	0 (5 (0 000))	0 / 5 / 0 000/)	0 / 0 / 0 000/
occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (an)	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 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 occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1
Erythema multiforme subjects affected / exposed	1 / E /20 000/ \	0 / 6 / 0 000/)	0 / 8 / 0 000/)
occurrences (all)	1 / 5 (20.00%)	0 / 6 (0.00%) 0	0 / 8 (0.00%)
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 occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
Night sweats	, and the second	, and the second	Ü
subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%)
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 occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%) 0	0 / 8 (0.00%)
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 occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
	Ŭ	Ü	
Muscle spasms subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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	О	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 /0 000/)	0 / 6 /0 000/)	0 / 0 / 0 000/)
occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Hypoglycaemia subjects affected / exposed	0 (5 (0 000))	0 (5 (0 000 ()	0 / 0 / 0 000/)
occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%) 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 /0 000/)	0 / 6 / 0 000/)	0.40.40.0004
occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%) 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 occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (an)	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 occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%)
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
	0	0	0
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
	0	0	0
Vaginal infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
	0	1	0
Viral rhinitis subjects affected / exposed occurrences (all)	0 / 5 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
	0	0	1

	i		
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 /0 000/)	0 / 4 /0 000/)	0 (24 (0 000()
	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 (0 000/)	0 / 4 /0 000/)	0 / 21 /0 000/)
	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
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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
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Immune system disorders			
Seasonal allergy subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)			
occurrences (an)	0	0	0
General disorders and administration site conditions			
Asthenia subjects affected / exposed	2 / 7 /20 570/ \	0 / 4 /0 000/ \	0 / 21 / 20 020/ \
	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 7 4 (0.00%)	0 / 31 (0.00 %)
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Chest pain	<u>l</u>		

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 occurrences (all)	0 / 7 (0.00%)	0 / 4 (0.00%) 0	0 / 31 (0.00%)
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	3 / 31 (9.68%)
occurrences (all)	0	0	4
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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	2 / 7 /42 060/	1 / 4 /25 000/)	0 / 21 / 25 010/)
	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
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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 occurrences (all)	0 / 7 (0.00%)	0 / 4 (0.00%)	2 / 31 (6.45%) 5
Cocarrences (any	0	U	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 (0 000/)	0 / 21 /0 000/)
occurrences (all)	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (un)	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 / / (26.3/%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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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	О
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)			
occurrences (un)	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 (an)	0	0	0
ı	1		
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
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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
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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)			
occurrences (an)	0	1	1
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 4 (0.00%)	3 / 31 (9.68%)
1	1 , , , , , , , ,	, , , ,	1

occurrences (all)

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 / / (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
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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 /0 000/)	0 / 4 /0 000/)	0 / 21 /0 000/)
	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

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 (0 000()	0 / / /0 000/	
	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 / 0 000/)	0 / 4 / 0 000/ 3	1 / 24 /2 222/
	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%)
000000000000000000000000000000000000000	ı		i l
occurrences (all)	0	0	1
	0	0	1
Musculoskeletal chest pain subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	1 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	1 1		
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 / 7 (0.00%)	0 0	0
Sinusitis subjects affected / exposed	0 (7 (0 000)	0 / 4 /0 000/	
occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	1 / 31 (3.23%) 1
Conjunctivitis subjects affected / exposed	0 / 7 /0 000/)	0 (4 (0 000))	0 / 21 / 0 000/)
occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	0 / 31 (0.00%) 0
Subcutaneous abscess			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%)	0 / 31 (0.00%) 0
Tonsillitis			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%)	0 / 31 (0.00%)
Upper respiratory tract infection	U	U	U
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 / / (14.2970)	0	0
Catheter site abscess subjects affected / exposed	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0 7 7 (0.00%)	0 7 4 (0.00%)	0 / 31 (0.00%)
Bronchitis			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 4 (0.00%) 0	0 / 31 (0.00%) 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 / 31 (0.00 /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 / 0 000/ \	0 /4 (0 00%)	0 / 21 /0 000/ \
222,2222 220004 / 220004	0 / 7 (0.00%)	0 / 4 (0.00%)	0 / 31 (0.00%)

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

Non-serious adverse events mg + Selicrelumab 12-21 mg (SC) mg + Selicrelumab 28-36 mg (SC) 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 occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Hott flush subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 1 / 9 (11.11%) Occurrences (all) 0 0 0 1 Hypertension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 0 0 Hypotension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 0 0 Intermittent claudication subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) Neoplasms benign, malignant and unspec				
adverse events subjects affected / exposed Vascular disorders Embolism subjects affected / exposed occurrences (ali) Hot flush subjects affected / exposed occurrences (ali) O Hypertension subjects affected / exposed occurrences (ali) O Hypertension subjects affected / exposed occurrences (ali) O O Hypotension subjects affected / exposed occurrences (ali) O O O Hypotension subjects affected / exposed occurrences (ali) O O O O Intermittent claudication subjects affected / exposed occurrences (ali) O O O Intermittent claudication subjects affected / exposed occurrences (ali) O O O O O Intermittent claudication subjects affected / exposed occurrences (ali) O O O O O Intermittent claudication subjects affected / exposed occurrences (ali) O O O O O O O O O O O O O	Non-serious adverse events	mg + Selicrelumab	mg + Selicrelumab	Part 1B: ATZ 1200 mg + Selicrelumab 48-64 mg (SC)
Subjects affected / exposed 16 / 16 (100.00%) 9 / 9 / 9 (100.00%) 9 / 9 / 9 / 9 / 9 / 9 / 9 / 9 / 9 / 9				
Vascular disorders Embolism subjects affected / exposed occurrences (all) Hot flush subjects affected / exposed occurrences (all) O O O O O O O O O O O O O		16 / 16 (100.00%)	9 / 9 (100.00%)	9 / 9 (100.00%)
subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Hot flush subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 1 / 9 (11.11%) 0 ccurrences (all) 0 0 1 Hypertension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 ccurrences (all) 0 0 0 0 Hypotension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 ccurrences (all) 0 0 0 0 1 Lymphoedema subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 Neoplasms benign, malignant and unspecified (incl cysts and polyps) 1 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) 0 Cancer pain 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%)	-		, , ,	, , ,
Occurrences (all)	Embolism			
Hot flush subjects affected / exposed occurrences (all) 0 0 1 Hypertension subjects affected / exposed occurrences (all) 0 0 0 1 Hypotension subjects affected / exposed occurrences (all) 0 0 0 0 Hypotension subjects affected / exposed occurrences (all) 0 0 0 0 Intermittent claudication subjects affected / exposed occurrences (all) 0 0 0 0 Intermittent claudication subjects affected / exposed occurrences (all) 0 0 0 0 Lymphoedema subjects affected / exposed occurrences (all) 0 0 0 0 Lymphoedema subjects affected / exposed occurrences (all) 0 0 0 0 Neonous thrombosis subjects affected / exposed occurrences (all) 1 0 0 0 Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 1 0 0 Cancer pain	subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 1 / 9 (11.11%) Hypertension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Hypotension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Intermittent claudication subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Lymphoedema subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Cancer pain 0 1 / 9 (11.11%) 0 / 9 (0.00%)	occurrences (all)	0	1	0
Occurrences (all)	Hot flush			
Neoplasms benign, malignant and unspecified (incl cysts affected / exposed occurrences (all) 0 0 0 0 0 0 0 0 0	subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Hypotension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 0 Intermittent claudication subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 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 occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Cancer pain 0 1 0 0 0	occurrences (all)			
subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Hypotension subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 0 Intermittent claudication subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 0 0 Lymphoedema subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Cancer pain 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%)				
occurrences (all) Hypotension subjects affected / exposed occurrences (all) O O O O O O O O O O O O O				
Hypotension Subjects affected / exposed O / 16 (0.00%) O / 9 (0.00%)	subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Intermittent claudication subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Occurrences (all) 0 0 0 Lymphoedema subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Cancer pain 0 1 0 0 0	occurrences (all)	0	0	0
occurrences (all) Intermittent claudication subjects affected / exposed occurrences (all) O O O O O O O O O O O O O	Hypotension			
occurrences (all) 0 0 0 Intermittent claudication subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) occurrences (all) 0 0 0 0 Lymphoedema subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Cancer pain 0 1 0 0	subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Lymphoedema subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Cancer pain 0 1 0 0	occurrences (all)			
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occurrences (all) Lymphoedema subjects affected / exposed occurrences (all) Venous thrombosis subjects affected / exposed occurrences (all) 1		0 / 16 (0 000/)	0 / 0 / 0 000/)	0 / 0 / 0 000/)
Lymphoedema 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) occurrences (all) 0 0 0 Venous thrombosis 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) 0 0 0 Anogenital warts 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) occurrences (all) 0 1 0		0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) Cancer pain 0 1 / 9 (11.11%) 0 / 9 (0.00%)	occurrences (all)	0	0	0
occurrences (all) Venous thrombosis subjects affected / exposed occurrences (all) Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) O / 16 (0.00%) O / 9 (0.00%) O / 9 (0.00%) O / 9 (0.00%) O / 9 (0.00%) O / 16 (0.00%) O / 1 / 9 (11.11%) O / 9 (0.00%) O / 1 / 9 (11.11%) O / 9 (0.00%) O / 1 / 9 (11.11%) O / 9 (0.00%)	Lymphoedema			
occurrences (all) Venous thrombosis subjects affected / exposed occurrences (all) 1 / 16 (6.25%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 9 (0.00%) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) 0 / 10 / 9 (0.00%) 0 / 10 / 9 (0.00%) 0 / 10 / 9 (0.00%) 0 / 10 / 9 (0.00%) 0 / 10 / 9 (0.00%) 0 / 10 / 9 (0.00%)	subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
subjects affected / exposed	occurrences (all)			
subjects affected / exposed	Venous thrombosis			
occurrences (all) 1 0 Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) 0 1/16 (0.00%) 1/9 (11.11%) 0/9 (0.00%) Cancer pain		1 / 16 /6 250/-)	0 / 0 (0 00%)	0 / 0 (0 00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) Cancer pain				
unspecified (incl cysts and polyps) Anogenital warts subjects affected / exposed occurrences (all) Cancer pain Unspecified (incl cysts and polyps) 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) 0	occurrences (all)	1	0	0
subjects affected / exposed 0 / 16 (0.00%) 1 / 9 (11.11%) 0 / 9 (0.00%) occurrences (all) 0 1 0 Cancer pain 0 0 0 0 0	unspecified (incl cysts and polyps)			
occurrences (all) 0 1 0 Cancer pain	subjects affected / exposed	0 / 16 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
	occurrences (all)			
	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 / 18 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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 occurrences (all)	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0	0 / 9 (0.00%) 0
Chest pain			, and the second
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	1		l I
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
Variant dischause			
Vaginal discharge subjects affected / exposed	0 / 16 (0.00%)	1 / 0 /11 110/)	0 / 9 (0.00%)
occurrences (all)		1 / 9 (11.11%)	
occurrences (an)	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)			
decarrences (un)	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%)
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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
	1		

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
	Ů	Ü	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
Coodination (air)	0	1	U
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)			
occurrences (un)	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 (0 000()	0 / 0 /0 000/)	0 / 0 / 0 000/)
occurrences (all)	0 / 16 (0.00%) 0	0 / 9 (0.00%) 0	0 / 9 (0.00%) 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 occurrences (all)	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (aii)	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 /12 500/ \	0.70.70.00%	0 / 0 / 0 000/)
occurrences (all)	2 / 16 (12.50%)	0 / 9 (0.00%)	0 / 9 (0.00%)
decarrences (an)	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 / 16 (6.25%)	0 / 9 (0.00%)	0 / 9 (0.00%)
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 (15 (0 000)	0 / 0 / 0 000/)	0 (0 (0 000)
occurrences (all)	0 / 16 (0.00%)	0 / 9 (0.00%) 0	0 / 9 (0.00%)
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 (0 000/)	1 / 0 /11 110/)	0 / 0 / 0 000/)
occurrences (all)	0 / 16 (0.00%)	1 / 9 (11.11%) 1	0 / 9 (0.00%)
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	1	1	I
subjects affected / exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)			
occarrences (any	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
decarrences (un)	0	U	
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)			
occurrences (un)	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
Uning my tage to active			
Urinary tract pain subjects affected / exposed	0 / 16 /0 000/	0 / 0 / 0 000/)	0 / 0 / 0 000/ >
Subjects affected / Exposed	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)

occurrences (un)	U	U	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 / 9 (0.00 /0)
(4.17)		U	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%)
l	-, 25 (5.25 %)	1	1

occurrences (all)

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 /6 250/	2 / 0 / 22 220/ \	2 / 0 / 22 220/ \
	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 F00/ \	1 / 0 /11 110/ \	0 / 0 / 0 000/)
	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 / 0 (0 000/)	0 / 0 / 0 000/)
		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 occurrences (all)	1 / 16 (6.25%) 1	0 / 9 (0.00%) 0	1 / 9 (11.11%)
	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 occurrences (all)	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
	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 /0 000/)	0 / 0 / 0 000/)	0 / 0 / 0 000/)
occurrences (all)	0 / 16 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (an)	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%)

1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 4 / 9 (44.44%) 6	0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 1 / 9 (11.11%)
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	0 / 9 (0.00%) 0 1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 0 / 9 (0.00%) 0 0 / 9 (0.00%)

Non-serious adverse events	Part 2 (SC): Small + Large Bowel Carcinoma		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 / 12 (0.00%)	0 7 14 (0.00%)	0 / 19 (0.00%)
Tumour pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
mmune 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 /0 000/ \	0 / 14 / 0 000/ \	0 / 10 / 0 000/ >
	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%)
		0 / 14 (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 (3.20%)
Injection site inflammation			
subjects affected / exposed	0 / 12 / 0 000/ \	0 / 14 / 0 000/ 3	1 / 10 / 5 0000
occurrences (all)	0 / 12 (0.00%) 0	0 / 14 (0.00%) 0	1 / 19 (5.26%) 1
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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
Turanaia			
Insomnia subjects affected / exposed	0 / 12 /0 000/)	1 / 14 / 7 140/)	2 / 10 /10 F20/ \
	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
Polyic pain			
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 occurrences (all)	0 / 12 (0.00%)	0 / 14 (0.00%) 0	0 / 19 (0.00%) 0
Vulvovaginal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 14 (0.00%) 0	0 / 19 (0.00%) 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
Dland quartining ingressed			
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 0	1 19 (3.20 %)
Blood urea increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
occurrences (all)			
court critical (uni)	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

increased	ı	1	I
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%)
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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	О	О
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
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Neutropenia subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	1 / 19 (5.26%)
occurrences (all)	0 / 12 (0.00 %)	1	1 (3.20%)
Thrombocytopenia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 14 (14.29%)	0 / 19 (0.00%)
occurrences (all)	1	3	0
lervous 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
Taska disaudan			
Taste disorder subjects affected / exposed	1 / 12 /0 220/ \	0 / 14 /0 000/)	0 / 10 /0 000/)
	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 14 (0.00 %)	1 (3.20 %)
		-	-
Maculopathy			0 / 42 /2 /2
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 occurrences (all)	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
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	О
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
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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	О
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 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
Clain availing			
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 (0 000/)	0 / 14 /0 000/)	0 / 10 (0 00%)
occurrences (all)	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
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 / 12 (0.00%)	2 / 14 (14.29%)	3
	_	_	_
Pain in extremity	0 (40 (5 5 5 5)	0./44/2-55	
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%)

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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
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Hyperthyroidism			
subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
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)			
occurrences (un)	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
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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	1	İ	2 / 40 /45 700/
1	0 / 12 (0.00%)	1 / 14 (7.14%)	3 / 19 (15.79%)
occurrences (all)	0 / 12 (0.00%)	1 / 14 (7.14%) 1	3 / 19 (15./9%)
Hyperglycaemia	0	1	3
Hyperglycaemia subjects affected / exposed	0 1 / 12 (8.33%)	1 0 / 14 (0.00%)	3 1 / 19 (5.26%)
Hyperglycaemia	0	1	3
Hyperglycaemia subjects affected / exposed	0 1 / 12 (8.33%)	1 0 / 14 (0.00%)	3 1 / 19 (5.26%)

occurrences (all)

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
Hypomagnosaomia			
Hypomagnesaemia subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	2 / 19 (10.53%)
occurrences (all)	0	1	3
Hyponatraemia	0 / 10 /0 000/	0 / 4 / / 0 000/)	2 / 10 /10 522/
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			

occurrences (all) 0 0 1 Fungal skin infection subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Gastroenteritis subjects affected / exposed occurrences (all) 1 / 12 (8.33%) 0 / 14 (0.00%) 0 / 19 (0.00%) Pneumonia subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 1 / 19 (5.26%) Oral candidiasis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 0 / 19 (0.00%) Occurrences (all) 0 1 / 14 (0.00%) 0 / 19 (0.00%) 0 / 19 (0.00%) Laryngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Occurrences (all) 0 0 0 0 Intervertebral discitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%)	subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
subjects affected / exposed occurrences (all) O / 12 (0.00%) O / 14 (0.00%) O / 19 (0.00%) O /	occurrences (all)	1	0	0
subjects affected / exposed occurrences (all) O / 12 (0.00%) O / 14 (0.00%) O / 19 (0.00%) O /	O al Wa			
occurrences (all) Skin infection subjects affected / exposed occurrences (all) O		0 / 12 (0 00%)	0 / 14 (0 00%)	1 / 19 (5 26%)
Skin infection subjects affected / exposed occurrences (all) O				
subjects affected / exposed occurrences (all) Sepsis subjects affected / exposed occurrences (all) Sepsis subjects affected / exposed occurrences (all) Fungal skin infection subjects affected / exposed occurrences (all) O	, ,		, and the second	_
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Sepsis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 1 / 19 (5.26%) 0 1 Fungal skin infection subjects affected / exposed occurrences (all) 0 0 0 0 Gastroenteritis subjects affected / exposed occurrences (all) 1 0 0 0 Pneumonia subjects affected / exposed occurrences (all) 0 0 0 1 / 14 (0.00%) 0 / 19 (
subjects affected / exposed occurrences (all) Fungal skin infection subjects affected / exposed occurrences (all) O	occurrences (all)	0	0	0
occurrences (all) Fungal skin infection subjects affected / exposed occurrences (all) Gastroenteritis subjects affected / exposed occurrences (all) Pneumonia subjects affected / exposed occurrences (all) 1	Sepsis			
Fungal skin infection subjects affected / exposed occurrences (all) 0 0 0 0 Gastroenteritis subjects affected / exposed occurrences (all) 1 1 0 0 0 Pneumonia subjects affected / exposed occurrences (all) 0 0 0 0 Pneumonia subjects affected / exposed occurrences (all) 0 0 0 1 1 19 (5.26%) occurrences (all) 0 0 3 Oral candidiasis subjects affected / exposed occurrences (all) 0 1 0 0 Lip infection subjects affected / exposed occurrences (all) 0 0 0 0 Lip infection subjects affected / exposed occurrences (all) 0 0 0 0 Laryngitis subjects affected / exposed occurrences (all) 0 0 0 0 Laryngitis subjects affected / exposed occurrences (all) 0 0 0 0 Intervertebral discitis subjects affected / exposed occurrences (all) 0 0 0 0 Nasopharyngitis subjects affected / exposed occurrences (all) 0 1 1 0 0 Nasopharyngitis subjects affected / exposed occurrences (all) 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Gastroenteritis subjects affected / exposed occurrences (all) 1 / 12 (8.33%) 0 / 14 (0.00%) 0 / 19 (0.00%) Pneumonia subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 1 / 19 (5.26%) Oral candidiasis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 0 / 19 (0.00%) Occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Durangitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Durangitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Durangitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%)	occurrences (all)	0	0	1
Occurrences (all) Gastroenteritis subjects affected / exposed occurrences (all) Pneumonia subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis occurrences (all) Oral candidasis occurrences (all) Oral candidasis occurrences (all) Oral (0.00%) Oral candidasis occurre	Fungal skin infection			
Gastroenteritis subjects affected / exposed occurrences (all) Pneumonia subjects affected / exposed occurrences (all) 1	-	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
subjects affected / exposed occurrences (all) 1 / 12 (8.33%) 0 / 14 (0.00%) 0 / 19 (0.00%) Pneumonia subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 1 / 19 (5.26%) Oral candidiasis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 0 / 19 (0.00%) Occurrences (all) 0 1 / 14 (0.00%) 0 / 19 (0.00%) Occurrences (all) 0 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Occurrences (all) 0 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 19 (0.00%) Occurrences (all) 0 0 / 14 (0.00%) 0 / 19 (0.00%)	occurrences (all)	0	0	0
occurrences (all) Pneumonia subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidiasis occurrences (all) Oral candidasis occurrences (all) Oral candidasis occurrences (all) Oral candida	Gastroenteritis			
Pneumonia subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 1 / 19 (5.26%) 0 3 Oral candidiasis subjects affected / exposed occurrences (all) 0 1 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0	subjects affected / exposed	1 / 12 (8.33%)	0 / 14 (0.00%)	0 / 19 (0.00%)
subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all) Oral candidates occurrences (all) Oral candidates occurrences (all) Oral candidates occurrences (all) Oral candidates occurrences (all) Oral candidates occurrences (all) Oral candidates occurrences (all) Oral candidates occurrences (all candidates occurrences (all	occurrences (all)	1	0	0
occurrences (all) 0 0 0 3 Oral candidiasis subjects affected / exposed occurrences (all) 0 1 0 1 0 1 0 1 0 1 0 Lip infection subjects affected / exposed occurrences (all) 0 1 0 0 1 0 0 1 0 0 1 0 0	Pneumonia			
Oral candidiasis subjects affected / exposed occurrences (all) Display the proof of the proof occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all)	subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	1 / 19 (5.26%)
subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 0 / 19 (0.00%) Lip infection subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Laryngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Intervertebral discitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) Occurrences (all) 0 1 / 14 (7.14%) 1 / 19 (5.26%)	occurrences (all)	0	0	3
occurrences (all) 0 1 0 Lip infection subjects affected / exposed occurrences (all) 0 0 0 0 0 0 0 0 0 0 1 0 0	Oral candidiasis			
Lip infection subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 19 (0.00%) 0 / 10 (0.00%) 0 / 10 (0.00%) 0 / 10 (0.00%) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) 0 / 19 (0.00%) 0 / 10	subjects affected / exposed	0 / 12 (0.00%)	1 / 14 (7.14%)	0 / 19 (0.00%)
subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Laryngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Intervertebral discitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) occurrences (all) 0 1 / 14 (7.14%) 1 / 19 (5.26%)	occurrences (all)	0	1	0
occurrences (all) 0 0 0 0 Laryngitis subjects affected / exposed occurrences (all) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Lip infection			
Laryngitis subjects affected / exposed	subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Intervertebral discitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) occurrences (all) 0 1 1	occurrences (all)	0	0	0
subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Intervertebral discitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) occurrences (all) 0 1 1	Laryngitis			
Intervertebral discitis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 0 Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) 1	• =	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%)	occurrences (all)	0	0	0
subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 0 / 14 (0.00%) 0 / 19 (0.00%) Nasopharyngitis subjects affected / exposed occurrences (all) 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%)	Intervertebral discitis			
Nasopharyngitis subjects affected / exposed 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) occurrences (all) 0 1 1		0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
subjects affected / exposed 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) occurrences (all) 0	occurrences (all)	0	0	0
subjects affected / exposed 0 / 12 (0.00%) 1 / 14 (7.14%) 1 / 19 (5.26%) occurrences (all) 0	Nasopharyngitis			
		0 / 12 (0.00%)	1 / 14 (7.14%)	1 / 19 (5.26%)
Infection	occurrences (all)			
	Infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Out formal infection			
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 (40 (0 000)		
occurrences (all)	0 / 12 (0.00%)	0 / 14 (0.00%)	0 / 19 (0.00%)
occurrences (aii)	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 17 13 (3.20 %)
Upper respiratory tract infection			
	1	I	I

	1	I	1
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)			
occurrences (un)	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 recoiratery tract infection			
Viral upper respiratory tract infection subjects affected / exposed		0 / 14 (0 000/)	0 / 10 / 0 000/)
	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: