Clinical trial results:
A Phase 1/2, Open-label, Multi-center Study of the Safety and Efficacy of KY1044 as Single Agent and in Combination With Anti-PD-L1 (Atezolizumab) in Adult Patients With Selected Advanced Malignancies

Summary

EudraCT number	2018-003172-12
Trial protocol	GB IT HU PL
Global end of trial date	03 October 2024

Results information

Result version number	v1 (current)
This version publication date	30 March 2025
First version publication date	30 March 2025

Trial information

Trial identification

Sponsor protocol code	KY1044-CT01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03829501
WHO universal trial number (UTN)	U1111-1269-6777
Other trial identifiers	Sanofi Study ID: TCD17370

Notes:

Sponsors

Sponsor organisation name	Kymab Ltd, a Sanofi company
Sponsor organisation address	The Eddeva Building (B920) Babraham Research Campus, Cambridge, United Kingdom, CB22 3AT
Public contact	Trial Transparency, Kymab Ltd, a Sanofi company, contact-US@sanofi.com
Scientific contact	Trial Transparency, Kymab Ltd, a Sanofi company, contact-US@sanofi.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 October 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 October 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of Phase 1 was to characterize the safety and tolerability of KY1044 as single agent and in combination with atezolizumab and to identify recommended doses for future studies. The main objective of Phase 2 was to estimate the anti-tumor efficacy of KY1044 as single agent and in combination with atezolizumab.

Protection of trial subjects:

Participants were fully informed of all pertinent aspects of clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the participant and considering the local culture. During the course of the trial, participants were provided with individual participant cards indicating the nature of the trial the participant is participating, contact details and any information needed in the event of a medical emergency. Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 January 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 46
Country: Number of subjects enrolled	United States: 93
Country: Number of subjects enrolled	Hungary: 3
Country: Number of subjects enrolled	Italy: 55
Country: Number of subjects enrolled	Taiwan: 25
Worldwide total number of subjects	222
EEA total number of subjects	58

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)	133
From 65 to 84 years	88
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 22 centers in 6 countries.

Pre-assignment

Screening details:

A total of 222 participants, of which 0 were screen failures. Participants were enrolled from 28 January 2019 to 04 August 2023.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Alomfilimab 0.8 mg

Arm description:

Participants received alomfilimab 0.8 mg as a single agent via intravenous (IV) infusion every 3 weeks (Q3W). The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed disease progression (PD) per immune-related (i) Response Evaluation Criteria in Solid Tumors (RECIST).

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Arm title	Alomfilimab 2.4 mg

Arm description:

Participants received alomfilimab 2.4 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Arm title	Alomfilimab 8 mg

Arm description:

Participants received alomfilimab 8 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose

received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Arm title	Alomfilimab 24 mg

Arm description:

Participants received alomfilimab 24 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Arm title	Alomfilimab 80 mg

Arm description:

Participants received alomfilimab 80 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Arm title	Alomfilimab 240 mg

Arm description:

Participants received alomfilimab 240 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Arm title	Alomfilimab 0.8 mg + Atezolizumab

Arm description:

Participants received alomfilimab 0.8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 2.4 mg + Atezolizumab

Arm description:

Participants received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 8 mg + Atezolizumab

Arm description:

Participants received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Arm type	Experimental

Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 24 mg + Atezolizumab

Arm description:

Participants received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Arm title	Alomfilimab 80 mg + Atezolizumab

Arm description:

Participants received alomfilimab 80 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	TECENTRIQ
Pharmaceutical forms	Concentrate for solution for infusion

Routes of administration	Intravenous use

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Arm description:

Anti-PD-(L)1 naïve participants with pancreatic cancer (PC) received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Arm description:

Anti-PD-(L)1 naïve participants with PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Arm description:

Anti-PD-(L)1 naïve participants with triple negative breast cancer (TNBC) received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD

per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Arm description:

Anti-PD-(L)1 naïve participants with TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Arm description:

Anti-PD-(L)1 naïve participants with Head and Neck Squamous Cell Carcinoma (HNSCC) received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Arm description:

Anti-PD-(L)1 naïve participants with HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Arm description:

Participants with pre-treated (PT) PC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Arm description:

Participants with PT PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV

infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Arm description:

Participants with PT TNBC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Arm description:

Participants with PT TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Arm description:

Participants with PT HNSCC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Arm title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Arm description:

Participants with PT HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Arm type	Experimental
Investigational medicinal product name	Alomfilimab
Investigational medicinal product code	KY1044
Other name	SAR445256
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A human anti-ICOS monoclonal antibody.

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

Dosage and administration details:

An anti-PD-L1 monoclonal antibody.

Number of subjects in period 1	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg
Started	4	5	9
Treated	4	5	9
Completed	0	1	0
Not completed	4	4	9
Withdrawal of Consent	2	-	3
Lost to Follow Up	-	-	-
PD	-	-	-
Death	2	4	5
Miscellaneous	-	-	1
Study Terminated by Sponsor	-	-	-

Number of subjects in period 1	Alomfilimab 24 mg	Alomfilimab 80 mg	Alomfilimab 240 mg
Started	8	7	5
Treated	8	7	5
Completed	0	0	0
Not completed	8	7	5
Withdrawal of Consent	-	1	1
Lost to Follow Up	-	1	-
PD	2	-	-
Death	6	5	4
Miscellaneous	-	-	-
Study Terminated by Sponsor	-	-	-

Number of subjects in period 1	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 8 mg + Atezolizumab
Started	5	43	36
Treated	5	43	36
Completed	0	3	1
Not completed	5	40	35
Withdrawal of Consent	-	10	10
Lost to Follow Up	-	2	2
PD	-	-	-
Death	5	24	22
Miscellaneous	-	1	-
Study Terminated by Sponsor	-	3	1

Number of subjects in period 1	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Started	9	9	15
Treated	9	9	15

Completed	0	0	0
Not completed	9	9	15
Withdrawal of Consent	3	4	4
Lost to Follow Up	-	2	1
PD	-	-	-
Death	6	3	10
Miscellaneous	-	-	-
Study Terminated by Sponsor	-	-	-

Number of subjects in period 1	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC
Started	14	7	14
Treated	14	7	14
Completed	0	1	0
Not completed	14	6	14
Withdrawal of Consent	4	-	3
Lost to Follow Up	-	1	1
PD	-	-	-
Death	10	5	7
Miscellaneous	-	-	-
Study Terminated by Sponsor	-	-	3

Number of subjects in period 1	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC
Started	5	5	2
Treated	5	5	2
Completed	0	0	0
Not completed	5	5	2
Withdrawal of Consent	-	1	1
Lost to Follow Up	-	-	-
PD	1	-	-
Death	2	2	1
Miscellaneous	-	-	-
Study Terminated by Sponsor	2	2	-

Number of subjects in period 1	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Started	1	1	6
Treated	1	1	6
Completed	0	0	0
Not completed	1	1	6

Withdrawal of Consent	-	-	3
Lost to Follow Up	-	-	-
PD	-	-	1
Death	1	1	1
Miscellaneous	-	-	-
Study Terminated by Sponsor	-	-	1

Number of subjects in period 1	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC
Started	3	9
Treated	3	8
Completed	1	0
Not completed	2	9
Withdrawal of Consent	-	1
Lost to Follow Up	-	1
PD	-	-
Death	2	3
Miscellaneous	-	1
Study Terminated by Sponsor	-	3

Reporting groups

Reporting group title	Alomfilimab 0.8 mg

Reporting group description:

Participants received alomfilimab 0.8 mg as a single agent via intravenous (IV) infusion every 3 weeks (Q3W). The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed disease progression (PD) per immune-related (i) Response Evaluation Criteria in Solid Tumors (RECIST).

Reporting group title	Alomfilimab 2.4 mg

Reporting group description:

Participants received alomfilimab 2.4 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg

Reporting group description:

Participants received alomfilimab 8 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Reporting group title	Alomfilimab 24 mg

Reporting group description:

Participants received alomfilimab 24 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 80 mg

Reporting group description:

Participants received alomfilimab 80 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 240 mg

Reporting group description:

Participants received alomfilimab 240 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 0.8 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 0.8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this

clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Reporting group title	Alomfilimab 24 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 80 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 80 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Reporting group description:

Anti-PD-(L)1 naïve participants with pancreatic cancer (PC) received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Reporting group description:

Anti-PD-(L)1 naïve participants with PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Reporting group description:

Anti-PD-(L)1 naïve participants with triple negative breast cancer (TNBC) received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Reporting group description:

Anti-PD-(L)1 naïve participants with TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Reporting group description:

Anti-PD-(L)1 naïve participants with Head and Neck Squamous Cell Carcinoma (HNSCC) received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Reporting group description:

Anti-PD-(L)1 naïve participants with HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Reporting group description:

Participants with pre-treated (PT) PC received alomfilimab 2.4 mg in combination with atezolizumab

1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Reporting group description:

Participants with PT PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Reporting group description:

Participants with PT TNBC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Reporting group description:

Participants with PT TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Reporting group description:

Participants with PT HNSCC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Reporting group description:

Participants with PT HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg
Number of subjects	4	5	9
Age categorical Units: Subjects			
>= 18 – 64 years	2	2	6
>= 65 to 84 years	2	3	3
>= 85 years	0	0	0
Gender categorical Units: Subjects			
Female	3	3	2
Male	1	2	7
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Black or African American	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
White	4	5	8
Other	0	0	0
Missing	0	0	0

Reporting group values	Alomfilimab 24 mg	Alomfilimab 80 mg	Alomfilimab 240 mg
Number of subjects	8	7	5
Age categorical Units: Subjects			
>= 18 – 64 years	2	4	3
>= 65 to 84 years	6	3	1
>= 85 years	0	0	1
Gender categorical Units: Subjects			
Female	6	3	3
Male	2	4	2
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Black or African American	0	1	0
Native Hawaiian or other Pacific Islander	0	0	0
White	8	5	5
Other	0	0	0
Missing	0	0	0

Reporting group values	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 8 mg + Atezolizumab
Number of subjects	5	43	36
Age categorical Units: Subjects			
>= 18 – 64 years	2	27	27
>= 65 to 84 years	3	16	9
>= 85 years	0	0	0
Gender categorical Units: Subjects			
Female	3	20	20
Male	2	23	16
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	9	6
Black or African American	0	1	1
Native Hawaiian or other Pacific Islander	0	0	0
White	5	30	28
Other	0	2	1
Missing	0	1	0

Reporting group values	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Number of subjects	9	9	15

Age categorical Units: Subjects			
>= 18 – 64 years	5	5	8
>= 65 to 84 years	4	4	7
>= 85 years	0	0	0
Gender categorical Units: Subjects			
Female	5	4	6
Male	4	5	9
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	3	0
Black or African American	1	0	0
Native Hawaiian or other Pacific Islander	0	0	0
White	6	6	14
Other	0	0	1
Missing	0	0	0

Reporting group values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC
Number of subjects	14	7	14
Age categorical Units: Subjects			
>= 18 – 64 years	5	6	10
>= 65 to 84 years	9	1	4
>= 85 years	0	0	0
Gender categorical Units: Subjects			
Female	6	7	14
Male	8	0	0
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Black or African American	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
White	14	7	13
Other	0	0	0
Missing	0	0	0

Reporting group values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC
Number of subjects	5	5	2
Age categorical Units: Subjects			
>= 18 – 64 years	3	4	1
>= 65 to 84 years	2	1	1

>= 85 years	0	0	0

Gender categorical Units: Subjects			
Female	0	1	0
Male	5	4	2
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Black or African American	0	1	0
Native Hawaiian or other Pacific Islander	0	0	0
White	4	3	2
Other	0	0	0
Missing	0	0	0

Reporting group values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Number of subjects	1	1	6
Age categorical Units: Subjects			
>= 18 – 64 years	0	1	4
>= 65 to 84 years	1	0	2
>= 85 years	0	0	0
Gender categorical Units: Subjects			
Female	0	1	6
Male	1	0	0
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2
Black or African American	0	0	1
Native Hawaiian or other Pacific Islander	0	0	0
White	1	1	3
Other	0	0	0
Missing	0	0	0

Reporting group values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Total
Number of subjects	3	9	222
Age categorical Units: Subjects			
>= 18 – 64 years	3	3	133
>= 65 to 84 years	0	6	88
>= 85 years	0	0	1

Gender categorical Units: Subjects			
Female	1	4	118
Male	2	5	104
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	28
Black or African American	2	0	8
Native Hawaiian or other Pacific Islander	0	0	0
White	1	8	181
Other	0	0	4
Missing	0	0	1

End points reporting groups

Reporting group title	Alomfilimab 0.8 mg

Reporting group description:

Participants received alomfilimab 0.8 mg as a single agent via intravenous (IV) infusion every 3 weeks (Q3W). The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed disease progression (PD) per immune-related (i) Response Evaluation Criteria in Solid Tumors (RECIST).

Reporting group title	Alomfilimab 2.4 mg

Reporting group description:

Participants received alomfilimab 2.4 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg

Reporting group description:

Participants received alomfilimab 8 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Reporting group title	Alomfilimab 24 mg

Reporting group description:

Participants received alomfilimab 24 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 80 mg

Reporting group description:

Participants received alomfilimab 80 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 240 mg

Reporting group description:

Participants received alomfilimab 240 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 0.8 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 0.8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this

clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Reporting group title	Alomfilimab 24 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 80 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 80 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Reporting group description:

Anti-PD-(L)1 naïve participants with pancreatic cancer (PC) received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Reporting group description:

Anti-PD-(L)1 naïve participants with PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Reporting group description:

Anti-PD-(L)1 naïve participants with triple negative breast cancer (TNBC) received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Reporting group description:

Anti-PD-(L)1 naïve participants with TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Reporting group description:

Anti-PD-(L)1 naïve participants with Head and Neck Squamous Cell Carcinoma (HNSCC) received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Reporting group description:

Anti-PD-(L)1 naïve participants with HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Reporting group description:

Participants with pre-treated (PT) PC received alomfilimab 2.4 mg in combination with atezolizumab

1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Reporting group description:

Participants with PT PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Reporting group description:

Participants with PT TNBC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Reporting group description:

Participants with PT TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Reporting group description:

Participants with PT HNSCC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Reporting group description:

Participants with PT HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Subject analysis set title	Alomfilimab 8 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received alomfilimab 8 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Subject analysis set title	Alomfilimab 8 mg + Atezolizumab
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Subject analysis set title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with PT HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Primary: Phase 1: Number of Participants Experiencing Treatment-emergent Adverse Events (TEAEs)

End point title	Phase 1: Number of Participants Experiencing Treatment-emergent Adverse Events (TEAEs)[1][2]

End point description:

An adverse event (AE) was any untoward medical occurrence in a participant administered a pharmaceutical product, which did not necessarily have a causal relationship with this treatment. An serious AE (SAE) was any AE that:
• resulted in death;
• was life-threatening;
• resulted in inpatient hospitalization or prolongation of existing hospitalization;
• resulted in a persistent or significant disability/incapacity;
• resulted in congenital anomaly/birth defect in the offspring of a participant who received IMPs;
• constituted an important medical event.

Clinically significant changes in laboratory parameters, vital signs and electrocardiogram results were reported as AEs. A TEAE was defined as an AE observed after starting administration of the specific treatment.

Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Primary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum duration of treatment exposure was up to approximately 212 weeks

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 additional statistics were pre-specified for this endpoint.

[2] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 24 mg	Alomfilimab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	7
Units: participants				
Any TEAEs	4	4	7	7
Any Serious TEAEs	1	1	2	3

End point values	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	43	9
Units: participants				
Any TEAEs	5	4	43	9
Any Serious TEAEs	2	2	17	4

End point values	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 8 mg	Alomfilimab 8 mg + Atezolizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9	10	35	
Units: participants				
Any TEAEs	9	8	34	

Any Serious TEAEs	3	3	11	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants Experiencing Dose Changes

End point title	Phase 1: Number of Participants Experiencing Dose

End point description:

Dose changes were defined as infusion interruption and dose reduction.

Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Primary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum duration of treatment exposure was up to approximately 212 weeks

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No additional statistics were pre-specified for this endpoint.

[4] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 24 mg	Alomfilimab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	7
Units: participants				
Infusion Interruption	1	0	1	1
Dose Reduction	0	0	0	0

End point values	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	43	9
Units: participants				
Infusion Interruption	0	0	2	0
Dose Reduction	0	0	0	0

End point values	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 8 mg	Alomfilimab 8 mg + Atezolizumab	

Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9	10	35	
Units: participants				
Infusion Interruption	2	0	0	
Dose Reduction	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Absolute Dose Intensity

End point title	Phase 1: Absolute Dose Intensity[5][6]

End point description:

Absolute dose intensity was calculated as cumulative dose received (mg) / study treatment duration (weeks).

Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Primary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum duration of treatment exposure was up to approximately 212 weeks

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No additional statistics were pre-specified for this endpoint.

[6] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 24 mg	Alomfilimab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	7
Units: mg/week				
arithmetic mean (standard deviation)	0.260 (± 0.0000)	0.778 (± 0.0179)	7.799 (± 0.2694)	26.174 (± 0.1952)

End point values	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	43	9
Units: mg/week				
arithmetic mean (standard deviation)	76.650 (± 4.8260)	0.236 (± 0.0288)	0.780 (± 0.0176)	7.418 (± 1.1455)

End point values	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 8 mg	Alomfilimab 8 mg + Atezolizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9	10	35	
Units: mg/week				
arithmetic mean (standard deviation)	25.774 (± 0.9037)	2.616 (± 0.0427)	2.573 (± 0.1159)	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Relative Dose Intensity

End point title	Phase 1: Relative Dose Intensity[7][8]

End point description:

Relative dose intensity was calculated as the cumulative dose received (mg) / initial planned cumulative dose (mg). Initial planned cumulative dose was calculated as the starting dose multiplied by the scheduled number of administrations within the study treatment duration.

Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Primary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum duration of treatment exposure was up to approximately 212 weeks

Notes:

[7] - 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 additional statistics were pre-specified for this endpoint.

[8] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 24 mg	Alomfilimab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	7
Units: ratio				
arithmetic mean (standard deviation)	0.988 (± 0.0189)	0.978 (± 0.0179)	1.015 (± 0.0835)	0.980 (± 0.0058)

End point values	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	43	9
Units: ratio				
arithmetic mean (standard deviation)	0.958 (± 0.0610)	0.884 (± 0.1071)	0.978 (± 0.0202)	0.928 (± 0.1422)

End point values	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 8 mg	Alomfilimab 8 mg + Atezolizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9	10	35	
Units: ratio				
arithmetic mean (standard deviation)	0.967 (± 0.0316)	0.979 (± 0.0179)	0.963 (± 0.0432)	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Overall Response Rate (ORR) Per RECIST 1.1

End point title	Phase 2: Overall Response Rate (ORR) Per RECIST 1.1[9][10]

End point description:

ORR was the percentage of participants with a measurable disease at baseline and with a confirmed response of complete response (CR) or partial response (PR) according to RECIST v1.1 as the best response. The response is confirmed by a later scan conducted at least 4 weeks after the initial response is observed. The 95% confidence interval (CI) was calculated using the exact binomial method (Clopper-Pearson).
CR: disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must have had a reduction in short axis to < 10 mm. All lymph nodes must have been non-pathological in size (< 10mm short axis).
PR: at least a 30% decrease in the sum of diameters of target lesions, taking as reference the Baseline sum diameters.

Full Analysis Set: all participants who were allocated to study drug, regardless of treatment ultimately received. The number of participants analyzed is inclusive of those with measurable disease at baseline only.

End point type	Primary

End point timeframe:

From first dose of study treatment (Day 1) up to the end of the long term follow-up, approximately 162 weeks

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No additional statistics were pre-specified for this endpoint.

[10] - 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: Endpoint was applicable for phase 2 only.

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	7	14
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 21.8)	0 (0.0 to 28.5)	0 (0.0 to 45.9)	7.1 (0.2 to 36.0)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	1
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 60.2)	0 (0.0 to 70.8)	0 (0.0 to 97.5)	0 (0.0 to 97.5)

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	6	3	8
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 97.5)	0 (0.0 to 52.2)	33.3 (0.8 to 90.6)	0 (0.0 to 41.0)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants Experiencing Dose Limiting Toxicities (DLTs)

End point title	Phase 1: Number of Participants Experiencing Dose Limiting Toxicities (DLTs)[11][12]

End point description:

A DLT was defined as a clinically relevant AE or abnormal laboratory value of Common Terminology Criteria for Adverse Events Version 5.0 (CTCAE v5.0) ≥ Grade 3 assessed as unrelated to disease, PD, inter-current illness or concomitant medications, which occurs within the first cycle (21 days) of treatment with alomfilimab as single agent or in combination with atezolizumab during the dose escalation part of the study.

Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Primary

End point timeframe:

From first dose of study treatment (Day 1) up to 21 days

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No additional statistics were pre-specified for this endpoint.

[12] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 24 mg	Alomfilimab 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	7
Units: participants	0	0	0	0

End point values	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	43	9
Units: participants	0	0	0	0

End point values	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 8 mg	Alomfilimab 8 mg + Atezolizumab	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9	10	35	
Units: participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR) Per RECIST 1.1

End point title	Best Overall Response (BOR) Per RECIST 1.1

End point description:

BOR for each participant was defined as the best confirmed response per RECIST 1.1 among all responses recorded from start of treatment until PD, initiation of new anti-cancer therapy, death, or analysis cut-off date, whichever comes first, with responses of:
CR: disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must have had a reduction in short axis to < 10 mm. All lymph nodes must have been non-pathological in size (< 10mm short axis).
PR: at least a 30% decrease in the sum of diameters of target lesions, taking as reference the Baseline sum diameters.
Stable disease (SD): neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD.
PD: at least a 20% increase in the sum of diameters of target lesions. The sum must also demonstrate an increase of at least 5mm. Unequivocal progression of existing non-target lesions.
Not evaluable (NE).

Analyzed in the Full Analysis Set.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to the end of the long term follow-up, approximately 236 and 162 weeks for Phase 1 and 2, respectively

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	9	8
Units: participants				
CR	0	0	0	0
PR	0	0	0	0
SD	1	0	2	2
PD	3	3	7	3
NE	0	2	0	3

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	5	43
Units: participants				
CR	0	0	0	1
PR	0	0	0	3
SD	2	1	3	12
PD	4	4	1	20
NE	1	0	1	7

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	9	9	15
Units: participants				
CR	0	0	0	0
PR	2	1	0	0
SD	8	1	4	6
PD	22	7	2	9
NE	4	0	3	0

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	7	14	5
Units: participants				
CR	0	0	0	0
PR	0	0	1	0

SD	0	1	4	2
PD	11	5	8	2
NE	3	1	1	1

End point values	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	1	1
Units: participants				
CR	0	0	0	0
PR	0	0	0	0
SD	1	0	1	0
PD	2	1	0	1
NE	2	1	0	0

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	9	
Units: participants				
CR	0	0	0	
PR	0	1	0	
SD	2	0	3	
PD	3	2	4	
NE	1	0	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) Per RECIST 1.1

End point title	Progression-free Survival (PFS) Per RECIST 1.1

End point description:

PFS was calculated as (first documented PD or death due to any cause - first dose date of study drug +1)/30.4375. Participants who were not observed to have progressed or died were censored at the date of the last tumor assessment. Participants who missed two or more sequential assessments were censored at the date of the last tumor assessment before the missed assessments. Participants who started new anti-cancer therapy prior to documented PD were censored at the date of the last tumor assessment prior to the start of the new therapy. Participants who did not have any tumor assessments were censored with a duration of 1 day. PFS was obtained via Kaplan Meier estimation using the Brookmeyer-Crowley method.
PD: at least a 20% increase in the sum of diameters of target lesions. The sum must also demonstrate an increase of at least 5mm. Unequivocal progression of existing non-target lesions.

Values of "-99999" or "99999" indicate N/A. Analyzed in the Full Analysis Set.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to the end of the long term follow-up, approximately 236 and 162 weeks for Phase 1 and 2, respectively

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	9	8
Units: months				
median (confidence interval 95%)	2 (2 to 99999)	2 (1 to 99999)	2 (1 to 6)	3 (1 to 99999)

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	5	43
Units: months				
median (confidence interval 95%)	2 (1 to 99999)	1 (1 to 99999)	3 (2 to 99999)	2 (2 to 4)

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	9	9	15
Units: months				
median (confidence interval 95%)	2 (2 to 2)	2 (1 to 4)	4 (2 to 99999)	2 (1 to 4)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	7	14	5
Units: months				
median (confidence interval 95%)	2 (2 to 2)	2 (1 to 99999)	2 (1 to 4)	4 (2 to 99999)

End point values	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	1	1
Units: months				
median (confidence interval 95%)	2 (1 to 99999)	2 (-99999 to 99999)	3 (-99999 to 99999)	2 (-99999 to 99999)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	8	
Units: months				
median (confidence interval 95%)	4 (2 to 99999)	2 (2 to 99999)	3 (2 to 4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response per RECIST 1.1

End point title	Duration of Response per RECIST 1.1

End point description:

Duration of response was calculated as (date of the first documentation of PD or to death due to any cause in the absence of PD - date of the first documentation of unconfirmed objective response [CR or PR] + 1]/30.4375. Participants who were not observed to have progressed or died were censored at the date of the last tumor assessment. Participants who missed two or more sequential assessments were censored at the date of the last tumor assessment before the missed assessments. Participants who started new anti-cancer therapy prior to documented PD were censored at the date of the last tumor assessment prior to the start of the new therapy. Participants with no disease assessment (or only had assessments with response = NE) after first study treatment or have assessments where the RECIST criteria could not be applied had their duration of response time censored. Duration of response was obtained via Kaplan Meier estimation.

Values of "-99999" or "99999" indicate N/A.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to the end of the long term follow-up, approximately 236 and 162 weeks for Phase 1 and 2, respectively

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[13]	0[14]	0[15]	0[16]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[13] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[14] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[15] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[16] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[17]	0[18]	1[19]	5[20]
Units: months				
median (confidence interval 95%)	(to)	(to)	11 (-99999 to 99999)	6 (2.1 to 99999)

Notes:

[17] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[18] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[19] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[20] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[21]	1[22]	0[23]	1[24]
Units: months				
median (confidence interval 95%)	99999 (13.9 to 99999)	11 (-99999 to 99999)	(to)	2 (-99999 to 99999)

Notes:

[21] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[22] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[23] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[24] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[25]	0[26]	1[27]	0[28]
Units: months				
median (confidence interval 95%)	(to)	(to)	13 (-99999 to 99999)	(to)

Notes:

[25] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[26] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

[27] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.
[28] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

End point values	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[29]	0[30]	0[31]	0[32]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:
[29] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.
[30] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.
[31] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.
[32] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[33]	1[34]	0[35]	
Units: months				
median (confidence interval 95%)	(to)	99999 (99999 to 99999)	(to)	

Notes:
[33] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.
[34] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.
[35] - Inclusive of those with observed events or participants that were censored. Analyzed in the FAS.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR Per iRECIST

End point title	ORR Per iRECIST

End point description:

RECIST 1.1 has been modified to take into consideration the unique response kinetics which have been observed with immunotherapy in some patients where responses to immune therapies may occur after progression has been assessed. ORR was the percentage of participants with a measurable disease at baseline and with a confirmed response of complete immune-response (iCR) or partial immune-response (iPR) according to iRECIST as the best response. The 95% CI was calculated using the exact binomial method (Clopper-Pearson).
iCR: disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must have had a reduction in short axis to < 10 mm. All lymph nodes must have been non-pathological in size (< 10mm short axis).
iPR: at least a 30% decrease in the sum of diameters of target lesions, taking as reference the Baseline sum diameters.

Analysed in the Full Analysis Set.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to the end of the long term follow-up, approximately 236 and 162 weeks for Phase 1 and 2, respectively

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	8
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 60.2)	0 (0.0 to 70.8)	0 (0.0 to 33.6)	0 (0.0 to 52.2)

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	4	41
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 60.2)	9.3 (3.1 to 26.1)

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	9	9	15
Units: percentage of participants				
number (confidence interval 95%)	5.6 (0.8 to 21.4)	11.1 (0.3 to 48.2)	0 (0.0 to 45.9)	0 (0.0 to 23.2)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	7	14	5
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 30.8)	0 (0.0 to 45.9)	7.1 (0.2 to 38.5)	0 (0.0 to 60.2)

End point values	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	1	1
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 70.8)	0 (0.0 to 97.5)	0 (0.0 to 97.5)	0 (0.0 to 97.5)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	8	
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 52.2)	33.3 (2.5 to 100.0)	0 (0.0 to 41.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: PFS Per iRECIST

End point title	PFS Per iRECIST

End point description:

PFS was calculated as (first documented iPD or death due to any cause - first dose date of study drug +1)/30.4375. Participants who were not observed to have progressed or died were censored at the date of the last tumor assessment. Participants who missed two or more sequential assessments were censored at the date of the last tumor assessment before the missed assessments. Participants who started new anti-cancer therapy prior to documented PD were censored at the date of the last tumor assessment prior to the start of the new therapy. Participants who did not have any tumor assessments were censored with a duration of 1 day. PFS was obtained via Kaplan Meier estimation using the Brookmeyer-Crowley method.
iPD: at least a 20% increase in the sum of diameters of target lesions. The sum must also demonstrate an increase of at least 5mm. Unequivocal progression of existing non-target lesions.

Values of "-99999" or "99999" indicate N/A. Analyzed in the Full Analysis Set.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to the end of the long term follow-up, approximately 236 and 162 weeks for Phase 1 and 2, respectively

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	9	8
Units: months				
median (confidence interval 95%)	7 (-99999 to 99999)	10 (4.2 to 99999)	10 (3.4 to 99999)	6 (3.3 to 99999)

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	5	43
Units: months				
median (confidence interval 95%)	6 (2.7 to 99999)	6 (3.4 to 99999)	4 (2.5 to 99999)	7 (5.5 to 10)

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	9	9	15
Units: months				
median (confidence interval 95%)	5 (2.8 to 9.9)	3 (1.8 to 4.0)	5 (4.6 to 99999)	5 (2.5 to 99999)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	7	14	5
Units: months				
median (confidence interval 95%)	5 (2.7 to 99999)	4 (2.6 to 99999)	10 (1.7 to 99999)	5 (5.0 to 99999)

End point values	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	1	1
Units: months				
median (confidence interval 95%)	4 (1.5 to 99999)	99999 (99999 to 99999)	10 (-99999 to 99999)	17 (-99999 to 99999)

End point values	Alomfilimab 8	Alomfilimab 8	Alomfilimab 24	

	mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	8	
Units: months				
median (confidence interval 95%)	12 (-99999 to 99999)	99999 (99999 to 99999)	6 (2.6 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: ORR Per RECIST 1.1

End point title	Phase 1: ORR Per RECIST 1.1[36]

End point description:

ORR was the percentage of participants with a measurable disease at baseline and with a confirmed response of CR or PR according to RECIST v1.1 as the best response. The response is confirmed by a later scan conducted at least 4 weeks after the initial response is observed. The 95% CI was calculated using the exact binomial method (Clopper-Pearson).
CR: disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must have had a reduction in short axis to < 10 mm. All lymph nodes must have been non-pathological in size (< 10mm short axis).
PR: at least a 30% decrease in the sum of diameters of target lesions, taking as reference the Baseline sum diameters.

Full Analysis Set: all participants who were allocated to study drug, regardless of treatment ultimately received. Inclusive of participants with measurable disease at baseline only.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to the end of the long term follow-up, approximately 236 weeks

Notes:

[36] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	8	8
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 60.2)	0 (0.0 to 70.8)	0 (0.0 to 33.6)	0 (0.0 to 52.2)

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	4	41
Units: percentage of participants				
number (confidence interval 95%)	0 (0.0 to 45.9)	0 (0.0 to 52.2)	0 (0.0 to 60.2)	9.3 (3.1 to

26.1)

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	9	9	
Units: percentage of participants				
number (confidence interval 95%)	5.6 (0.8 to 20.8)	11.1 (0.3 to 48.2)	0 (0.0 to 45.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival Rate at 12 and 24 Months

End point title	Overall Survival Rate at 12 and 24 Months

End point description:

Overall Survival rate was defined as the proportion of participants that had known survival status. Overall survival rate was obtained via Kaplan Meier estimation using the complimentary log-log transformation method.

Values of "-99999" and "99999" represent N/A. Full Analysis Set: all participants who were allocated to study drug, regardless of treatment ultimately received.

End point type	Secondary

End point timeframe:

Months 12 and 24

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	9	8
Units: proportion of participants				
number (confidence interval 95%)				
12 months	0.0 (-99999 to 99999)	0.2 (0.01 to 0.58)	0.4 (0.10 to 0.73)	0.3 (0.04 to 0.56)
24 months	0.0 (-99999 to 99999)	0.2 (0.01 to 0.58)	0.3 (0.04 to 0.61)	99999 (99999 to 99999)

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	5	43
Units: proportion of participants				

number (confidence interval 95%)				
12 months	0.4 (0.10 to 0.73)	0.0 (-99999 to 99999)	0.4 (0.05 to 0.75)	0.4 (0.27 to 0.60)
24 months	0.0 (-99999 to 99999)	0.0 (-99999 to 99999)	0.0 (-99999 to 99999)	0.3 (0.13 to 0.43)

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	9	9	15
Units: proportion of participants				
number (confidence interval 95%)				
12 months	0.4 (0.22 to 0.57)	0.2 (0.01 to 0.64)	0.5 (0.12 to 0.82)	0.2 (0.03 to 0.47)
24 months	0.3 (0.11 to 0.44)	0.0 (-99999 to 99999)	99999 (99999 to 99999)	0.0 (-99999 to 99999)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	7	14	5
Units: proportion of participants				
number (confidence interval 95%)				
12 months	0.0 (-99999 to 99999)	0.6 (0.17 to 0.84)	0.7 (0.38 to 0.88)	99999 (99999 to 99999)
24 months	0.0 (-99999 to 99999)	0.2 (0.01 to 0.56)	0.4 (0.13 to 0.66)	99999 (99999 to 99999)

End point values	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	1	1
Units: proportion of participants				
number (confidence interval 95%)				
12 months	99999 (99999 to 99999)	99999 (99999 to 99999)	0.0 (-99999 to 99999)	99999 (99999 to 99999)
24 months	99999 (99999 to 99999)	99999 (99999 to 99999)	0.0 (-99999 to 99999)	0.0 (-99999 to 99999)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	9	
Units: proportion of participants				
number (confidence interval 95%)				
12 months	99999 (99999 to 99999)	0.3 (0.01 to 0.77)	99999 (99999 to 99999)	
24 months	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants Experiencing TEAEs

End point title	Phase 2: Number of Participants Experiencing TEAEs[37]

End point description:

An AE was any untoward medical occurrence in a participant administered a pharmaceutical product, which did not necessarily have a causal relationship with this treatment. An SAE was any AE that:
resulted in death;
- was life-threatening;
- resulted in inpatient hospitalization or prolongation of existing hospitalization;
- resulted in a persistent or significant disability/incapacity;
- resulted in congenital anomaly/birth defect in the offspring of a participant who received IMPs;
- constituted an important medical event.

Clinically significant changes in laboratory parameters, vital signs and electrocardiogram results were reported as AEs. A TEAE was defined as an AE observed after starting administration of the specific treatment.

Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum duration of treatment exposure was up to approximately 86 weeks

Notes:

[37] - 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: Endpoint was applicable for phase 2 only.

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	7	14
Units: participants				

Any TEAEs	15	13	7	14
Any Serious TEAEs	6	2	1	2

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	1
Units: participants				
Any TEAEs	5	5	2	1
Any Serious TEAEs	1	1	1	0

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	6	3	8
Units: participants				
Any TEAEs	1	6	3	8
Any Serious TEAEs	0	2	1	4

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants Experiencing Dose Changes

End point title	Phase 2: Number of Participants Experiencing Dose Changes[38]

End point description:

Dose changes were defined as infusion interruption and dose reduction.

Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum duration of treatment exposure was up to approximately 86 weeks

Notes:

[38] - 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: Endpoint was applicable for phase 2 only.

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	7	14
Units: participants				
Infusion Interruption	0	0	0	0
Dose Reduction	0	0	0	2

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	1
Units: participants				
Infusion Interruption	1	0	0	0
Dose Reduction	0	1	0	0

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	6	3	8
Units: participants				
Infusion Interruption	0	1	1	0
Dose Reduction	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Absolute Dose Intensity

End point title	Phase 2: Absolute Dose Intensity[39]

End point description:

Absolute dose intensity was calculated as cumulative dose received (mg) / study treatment duration (weeks).

Values of "99999" represent N/A. Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum

duration of treatment exposure was up to approximately 86 weeks

Notes:

[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: Endpoint was applicable for phase 2 only.

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	7	14
Units: mg/week				
arithmetic mean (standard deviation)	0.778 (± 0.0540)	2.559 (± 0.1712)	0.777 (± 0.0111)	2.536 (± 0.1628)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	1
Units: mg/week				
arithmetic mean (standard deviation)	2.366 (± 0.3577)	6.818 (± 2.3926)	0.775 (± 0.0212)	2.640 (± 99999)

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	6	3	8
Units: mg/week				
arithmetic mean (standard deviation)	0.760 (± 99999)	2.607 (± 0.0841)	2.613 (± 0.0551)	7.794 (± 0.1676)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Relative Dose Intensity

End point title	Phase 2: Relative Dose Intensity[40]

End point description:

Relative dose intensity was calculated as the cumulative dose received (mg) / initial planned cumulative dose (mg). Initial planned cumulative dose was calculated as the starting dose multiplied by the scheduled number of administrations within the study treatment duration.

Values of "99999" represent N/A. Safety Analysis Set: all participants who took at least one dose of study drug within the relevant phase. Participants were grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to 30 days post last dose of study treatment; maximum duration of treatment exposure was up to approximately 86 weeks

Notes:

[40] - 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: Endpoint was applicable for phase 2 only.

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	14	7	14
Units: ratio				
arithmetic mean (standard deviation)	0.973 (± 0.0660)	0.956 (± 0.0638)	0.976 (± 0.0113)	1.014 (± 0.1256)

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	1
Units: ratio				
arithmetic mean (standard deviation)	0.886 (± 0.1316)	0.980 (± 0.0274)	0.975 (± 0.0212)	0.990 (± 99999)

End point values	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	6	3	8
Units: ratio				
arithmetic mean (standard deviation)	0.960 (± 99999)	0.977 (± 0.0333)	0.980 (± 0.0200)	0.973 (± 0.0191)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Maximum concentration (Cmax) of Alomfilimab

End point title	Phase 1: Maximum concentration (Cmax) of Alomfilimab[41]

End point description:

The serum pharmacokinetics (PK) of alomfilimab were characterized using non-compartmental analysis (NCA). Nominal times of sample collections were used for the NCA. All below limit of quantification (BLQ) values were set to 0 units.

PK Evaluable Set: consisted of all participants who had sufficient concentration-time data within the relevant phase to permit calculation of PK parameters for alomfilimab.

End point type	Secondary

End point timeframe:

Cycles 1 and 3 Day 1 pre-infusion to 336 hours post-infusion start (21 day cycle length)

Notes:

[41] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	9	7
Units: ug/mL				
arithmetic mean (standard deviation)				
Cycle 1 (n = 4, 5, 9, 7, 7, 5, 5, 35, 29, 8, 9)	0.3022 (± 0.12476)	0.9773 (± 0.29919)	3.3327 (± 0.95752)	8.7301 (± 2.84671)
Cycle 3 (n = 3, 2, 7, 3, 5, 2, 3, 25, 21, 5, 6)	0.2671 (± 0.06805)	1.2029 (± 0.24583)	3.7461 (± 0.86853)	30.5647 (± 39.72256)

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	5	35
Units: ug/mL				
arithmetic mean (standard deviation)				
Cycle 1 (n = 4, 5, 9, 7, 7, 5, 5, 35, 29, 8, 9)	33.7844 (± 12.98646)	124.4294 (± 79.79754)	0.3339 (± 0.17905)	1.1201 (± 0.66885)
Cycle 3 (n = 3, 2, 7, 3, 5, 2, 3, 25, 21, 5, 6)	43.8045 (± 14.07259)	141.8131 (± 62.54794)	0.2840 (± 0.24914)	1.6449 (± 3.01380)

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	8	9	
Units: ug/mL				
arithmetic mean (standard deviation)				

Cycle 1 (n = 4, 5, 9, 7, 7, 5, 5, 35, 29, 8, 9)	3.3476 (± 1.23416)	8.2597 (± 2.75396)	31.4793 (± 10.38008)	
Cycle 3 (n = 3, 2, 7, 3, 5, 2, 3, 25, 21, 5, 6)	9.5099 (± 28.23379)	10.2883 (± 3.86029)	51.6622 (± 41.65071)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Half-life (t1/2) of Alomfilimab

End point title	Phase 1: Half-life (t1/2) of Alomfilimab[42]

End point description:

The serum PK of alomfilimab were characterized using NCA. Nominal times of sample collections were used for the NCA. All BLQ values were set to 0 units.

Values of "99999" represent N/A. PK Evaluable Set: consisted of all participants who had sufficient concentration-time data within the relevant phase to permit calculation of PK parameters for alomfilimab.

End point type	Secondary

End point timeframe:

Cycles 1 and 3 Day 1 pre-infusion to 336 hours post-infusion start (21 day cycle length)

Notes:

[42] - 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: Endpoint was applicable for phase 1 only.

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	9	8
Units: hours				
arithmetic mean (standard deviation)				
Cycle 1 (n = 4, 5, 9, 8, 7, 5, 4, 36, 30, 8, 9)	42.7633 (± 20.84762)	72.2276 (± 9.56084)	149.0872 (± 55.14152)	226.2922 (± 75.20291)
Cycle 3 (n = 0, 1, 5, 2, 5, 1, 0, 15, 14, 2, 5)	99999 (± 99999)	80.3268 (± 99999)	215.6472 (± 98.90118)	358.6064 (± 143.16181)

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	5	4	36
Units: hours				
arithmetic mean (standard deviation)				
Cycle 1 (n = 4, 5, 9, 8, 7, 5, 4, 36, 30, 8, 9)	377.5444 (± 126.28273)	356.4297 (± 109.96450)	37.4777 (± 3.96733)	93.0339 (± 33.82676)
Cycle 3 (n = 0, 1, 5, 2, 5, 1, 0, 15, 14, 2, 5)	342.6067 (± 193.81667)	273.6673 (± 99999)	99999 (± 99999)	116.0599 (± 42.16269)

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	8	9	
Units: hours				
arithmetic mean (standard deviation)				
Cycle 1 (n = 4, 5, 9, 8, 7, 5, 4, 36, 30, 8, 9)	165.8783 (± 89.07566)	174.9685 (± 79.39134)	300.0089 (± 113.49910)	
Cycle 3 (n = 0, 1, 5, 2, 5, 1, 0, 15, 14, 2, 5)	202.0099 (± 78.48781)	230.5514 (± 103.13822)	440.0235 (± 236.99886)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Anti-drug Antibodies (ADA) at Anytime

End point title	Number of Participants Experiencing Anti-drug Antibodies (ADA) at Anytime

End point description:

Detection of ADA was assessed from blood samples taken during the study using validated bioanalytical methods. The number of participants who developed detectable anti-alomfilimab or anti-atezolizumab antibodies during any cycle or the safety follow-up period (SFUP) was calculated.

Values of "99999" represent N/A. Anti-drug Antibody Evaluable Set: consisted of all participants who received at least one dose of alomfilimab or atezolizumab and had ADA results available for analysis within the relevant phase.

End point type	Secondary

End point timeframe:

Phase 1: pre-infusion at all cycles (up to 69 cycles) + 90 days SFUP; Phase 2: pre-infusion at all cycles (up to 28 cycles) + 90 day SFUP (21 day cycle length)

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4[43]	3[44]	8[45]	8[46]
Units: participants				
≥ 1 Positive Anti-alomfilimab Antibodies Result	1	0	2	1
≥ 1 Positive Anti-atezolizumab Antibodies Result	99999	99999	99999	99999

Notes:

[43] - Anti-alomfilimab n = 4; Anti-atezolizumab n = 0.

[44] - Anti-alomfilimab n = 3; Anti-atezolizumab n = 0.

[45] - Anti-alomfilimab n = 8; Anti-atezolizumab n = 0.

[46] - Anti-alomfilimab n = 8; Anti-atezolizumab n = 0.

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[47]	5[48]	5[49]	36[50]
Units: participants				
≥ 1 Positive Anti-alomfilimab Antibodies Result	1	0	2	9
≥ 1 Positive Anti-atezolizumab Antibodies Result	99999	99999	1	8

Notes:

[47] - Anti-alomfilimab n = 7; Anti-atezolizumab n = 0.

[48] - Anti-alomfilimab n = 5; Anti-atezolizumab n = 0.

[49] - Anti-alomfilimab n = 5; Anti-atezolizumab n = 5.

[50] - Anti-alomfilimab n = 36; Anti-atezolizumab n = 36.

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34[51]	8[52]	6[53]	13[54]
Units: participants				
≥ 1 Positive Anti-alomfilimab Antibodies Result	8	0	0	1
≥ 1 Positive Anti-atezolizumab Antibodies Result	8	4	1	5

Notes:

[51] - Anti-alomfilimab n = 34; Anti-atezolizumab n = 34.

[52] - Anti-alomfilimab n = 8; Anti-atezolizumab n = 8.

[53] - Anti-alomfilimab n = 6; Anti-atezolizumab n = 6.

[54] - Anti-alomfilimab n = 13; Anti-atezolizumab n = 13.

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11[55]	6[56]	12[57]	5[58]
Units: participants				
≥ 1 Positive Anti-alomfilimab Antibodies Result	2	1	0	3
≥ 1 Positive Anti-atezolizumab Antibodies Result	2	1	0	1

Notes:

[55] - Anti-alomfilimab n = 11; Anti-atezolizumab n = 11.

[56] - Anti-alomfilimab n = 6; Anti-atezolizumab n = 6.

[57] - Anti-alomfilimab n = 12; Anti-atezolizumab n = 12.

[58] - Anti-alomfilimab n = 4; Anti-atezolizumab n = 5.

End point values	Alomfilimab 24 mg +	Alomfilimab 2.4 mg +	Alomfilimab 8 mg +	Alomfilimab 2.4 mg +

	Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Atezolizumab in Anti-PD-(L)1 PT PC	Atezolizumab in Anti-PD-(L)1 PT PC	Atezolizumab in Anti-PD-(L)1 PT TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[59]	1[60]	1[61]	0[62]
Units: participants				
≥ 1 Positive Anti-alomfilimab Antibodies Result	99999	1	0	
≥ 1 Positive Anti-atezolizumab Antibodies Result	0	0	0	

Notes:

[59] - Anti-alomfilimab n = 0; Anti-atezolizumab n = 3.

[60] - Anti-alomfilimab n = 1; Anti-atezolizumab n = 1.

[61] - Anti-alomfilimab n = 1; Anti-atezolizumab n = 1.

[62] - Anti-alomfilimab n = 0; Anti-atezolizumab n = 0.

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6[63]	3[64]	7[65]	
Units: participants				
≥ 1 Positive Anti-alomfilimab Antibodies Result	0	1	99999	
≥ 1 Positive Anti-atezolizumab Antibodies Result	0	1	1	

Notes:

[63] - Anti-alomfilimab n = 6; Anti-atezolizumab n = 6.

[64] - Anti-alomfilimab n = 3; Anti-atezolizumab n = 3.

[65] - Anti-alomfilimab n = 0; Anti-atezolizumab n = 7.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Tumor-infiltrating Lymphocytes per mm^2 at Cycle 2 Day 8

End point title	Change from Baseline in Tumor-infiltrating Lymphocytes per mm^2 at Cycle 2 Day 8

End point description:

Biological samples (e.g., archived and fresh tumor samples or blood samples) were collected for analysis of responsive biomarkers.

The summary of change in the following markers were calculated:
- FOXP3-ICOS double-positive cells per mm^2 in the Tumor
- CD8-positive cells per mm^2 in the tumor
- CD8-positive cells per mm^2 in the invasive margin.

Values of "99999" represent N/A. Biomarker Evaluable Set: consisted of all participants who received at least one dose of study drug and had at least one of ICOS, FOXP3 and CD8 cells results available for analysis within the relevant phase.

End point type	Secondary

End point timeframe:

Baseline and Cycle 2 Day 8 (21 day cycle length)

End point values	Alomfilimab 0.8 mg	Alomfilimab 2.4 mg	Alomfilimab 8 mg	Alomfilimab 24 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[66]	3[67]	7[68]	3[69]
Units: cells per mm^2				
arithmetic mean (standard deviation)				
FOXP3-ICOS double-positive cells in tumor	0.275 (± 5.5649)	21.905 (± 30.1015)	-50.323 (± 42.9514)	-42.210 (± 26.6714)
CD8-positive cells in tumor	-449.920 (± 99999)	448.833 (± 443.5399)	47.126 (± 294.7947)	-105.110 (± 190.2826)
CD8-positive cells in invasive margin	99999 (± 99999)	99999 (± 99999)	-229.600 (± 114.8200)	99999 (± 99999)

Notes:

[66] - FOXP3-ICOS n = 2; CD8-positive in tumor n = 1; CD8-positive in invasive margin n = 0.

[67] - FOXP3-ICOS n = 2; CD8-positive in tumor n = 3; CD8-positive in invasive margin n = 0.

[68] - FOXP3-ICOS n = 6; CD8-positive in tumor n = 7; CD8-positive in invasive margin n = 2.

[69] - FOXP3-ICOS n = 3; CD8-positive in tumor n = 3; CD8-positive in invasive margin n = 0.

End point values	Alomfilimab 80 mg	Alomfilimab 240 mg	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[70]	3[71]	3[72]	16[73]
Units: cells per mm^2				
arithmetic mean (standard deviation)				
FOXP3-ICOS double-positive cells in tumor	-29.318 (± 28.0896)	-67.160 (± 59.7524)	-18.860 (± 33.2369)	-129.334 (± 118.3340)
CD8-positive cells in tumor	-11.532 (± 169.8503)	-371.857 (± 884.7449)	-218.017 (± 282.9603)	111.154 (± 939.3540)
CD8-positive cells in invasive margin	336.140 (± 99999)	99999 (± 99999)	-422.680 (± 99999)	99999 (± 99999)

Notes:

[70] - FOXP3-ICOS n = 5; CD8-positive in tumor n = 5; CD8-positive in invasive margin n = 1.

[71] - FOXP3-ICOS n = 3; CD8-positive in tumor n = 3; CD8-positive in invasive margin n = 0.

[72] - FOXP3-ICOS n = 3; CD8-positive in tumor n = 3; CD8-positive in invasive margin n = 1.

[73] - FOXP3-ICOS n = 16; CD8-positive in tumor n = 14; CD8-positive in invasive margin n = 0.

End point values	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16[74]	3[75]	3[76]	8[77]
Units: cells per mm^2				
arithmetic mean (standard deviation)				
FOXP3-ICOS double-positive cells in tumor	-90.589 (± 115.9495)	-117.610 (± 174.4591)	-3.653 (± 6.5269)	-58.865 (± 65.7823)
CD8-positive cells in tumor	174.339 (± 693.8745)	300.433 (± 325.6656)	21.925 (± 56.3211)	202.501 (± 588.9525)
CD8-positive cells in invasive margin	99999 (± 99999)	-163.910 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[74] - FOXP3-ICOS n = 14; CD8-positive in tumor n = 16; CD8-positive in invasive margin n = 0.

[75] - FOXP3-ICOS n = 3; CD8-positive in tumor n = 3; CD8-positive in invasive margin n = 1.

[76] - FOXP3-ICOS n = 3; CD8-positive in tumor n = 2; CD8-positive in invasive margin n = 0.

[77] - FOXP3-ICOS n = 6; CD8-positive in tumor n = 8; CD8-positive in invasive margin n = 0.

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5[78]	4[79]	8[80]	1[81]
Units: cells per mm^2				
arithmetic mean (standard deviation)				
FOXP3-ICOS double-positive cells in tumor	-45.618 (± 34.5880)	-51.293 (± 56.8048)	-76.331 (± 63.0946)	-437.660 (± 99999)
CD8-positive cells in tumor	-63.528 (± 65.5904)	318.470 (± 385.7782)	320.923 (± 685.1093)	-116.950 (± 99999)
CD8-positive cells in invasive margin	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[78] - FOXP3-ICOS n = 5; CD8-positive in tumor n = 5; CD8-positive in invasive margin n = 0.

[79] - FOXP3-ICOS n = 4; CD8-positive in tumor n = 3; CD8-positive in invasive margin n = 0.

[80] - FOXP3-ICOS n = 8; CD8-positive in tumor n = 8; CD8-positive in invasive margin n = 0.

[81] - FOXP3-ICOS n = 1; CD8-positive in tumor n = 1; CD8-positive in invasive margin n = 0.

End point values	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[82]	0[83]	1[84]	0[85]
Units: cells per mm^2				
arithmetic mean (standard deviation)				
FOXP3-ICOS double-positive cells in tumor	-518.975 (± 668.5624)	()	-31.120 (± 99999)	()
CD8-positive cells in tumor	-1009.800 (± 99999)	()	-34.840 (± 99999)	()
CD8-positive cells in invasive margin	99999 (± 99999)	()	99999 (± 99999)	()

Notes:

[82] - FOXP3-ICOS n = 2; CD8-positive in tumor n = 1; CD8-positive in invasive margin n = 0.

[83] - FOXP3-ICOS n = 0; CD8-positive in tumor n = 0; CD8-positive in invasive margin n = 0.

[84] - FOXP3-ICOS n = 1; CD8-positive in tumor n = 1; CD8-positive in invasive margin n = 0.

[85] - FOXP3-ICOS n = 0; CD8-positive in tumor n = 0; CD8-positive in invasive margin n = 0.

End point values	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2[86]	1[87]	3[88]	
Units: cells per mm^2				
arithmetic mean (standard deviation)				

FOXP3-ICOS double-positive cells in tumor	-149.445 (± 137.0019)	-197.940 (± 99999)	-397.437 (± 307.3676)	
CD8-positive cells in tumor	181.120 (± 147.3752)	-39.600 (± 99999)	171.170 (± 293.3937)	
CD8-positive cells in invasive margin	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	

Notes:

[86] - FOXP3-ICOS n = 2; CD8-positive in tumor n = 2; CD8-positive in invasive margin n = 0.

[87] - FOXP3-ICOS n = 1; CD8-positive in tumor n = 1; CD8-positive in invasive margin n = 0.

[88] - FOXP3-ICOS n = 3; CD8-positive in tumor n = 3; CD8-positive in invasive margin n = 0.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

AEs: up to 30 days post last dose of study treatment, approximately 216 and 90 weeks for Phase 1 and 2, respectively; All-cause mortality: up to the end of the long term follow-up, approximately 236 and 162 weeks for Phase 1 and 2, respectively

Adverse event reporting additional description:

Presented per the Safety Analysis Set with participants grouped according to the study drug received at Cycle 1 Day 1 (21-day cycle length).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Alomfilimab 8 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 0.8 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 0.8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 240 mg

Reporting group description:

Participants received alomfilimab 240 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 80 mg

Reporting group description:

Participants received alomfilimab 80 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg

Reporting group description:

Participants received alomfilimab 24 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg

Reporting group description:

Participants received alomfilimab 8 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

One participant was planned to receive alomfilimab 8 mg + atezolizumab; however, the actual dose received was alomfilimab 8 mg. For the Safety Analysis Set, this participant was counted under actual dose received (alomfilimab 8 mg).

Reporting group title	Alomfilimab 2.4 mg

Reporting group description:

Participants received alomfilimab 2.4 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 0.8 mg

Reporting group description:

Participants received alomfilimab 0.8 mg as a single agent via IV infusion Q3W. The participants continued treatment with alomfilimab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Reporting group description:

Participants with PT PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Reporting group description:

Participants with PT TNBC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC

Reporting group description:

Participants with PT TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Reporting group description:

Anti-PD-(L)1 naïve participants with HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Reporting group description:

Anti-PD-(L)1 naïve participants with PC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC

Reporting group description:

Participants with PT PC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab

within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 80 mg + Atezolizumab

Reporting group description:

Participants received alomfilimab 80 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC

Reporting group description:

Anti-PD-(L)1 naïve participants with HNSCC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Reporting group description:

Anti-PD-(L)1 naïve participants with TNBC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC

Reporting group description:

Anti-PD-(L)1 naïve participants with TNBC received alomfilimab 2.4 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC

Reporting group description:

Anti-PD-(L)1 naïve participants with PC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Reporting group description:

Participants with PT HNSCC received alomfilimab 24 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Reporting group title	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC

Reporting group description:

Participants with PT HNSCC received alomfilimab 8 mg in combination with atezolizumab 1200 mg via IV infusion Q3W. The participants continued treatment with alomfilimab in combination with atezolizumab within this clinical study, as long as they continued to derive benefit from treatment, until the participant experienced unacceptable toxicity or confirmed PD per iRECIST.

Serious adverse events	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 35 (31.43%)	17 / 43 (39.53%)	4 / 9 (44.44%)
number of deaths (all causes)	21	24	6
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			

subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Oesophageal carcinoma			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Tumour associated fever			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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 / 35 (0.00%)	0 / 43 (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 / 35 (0.00%)	0 / 43 (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
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Hypotension			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
General disorders and administration site conditions			

Chills			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Chest pain			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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 / 1	0 / 0
Face oedema			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Medical device discomfort			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Fatigue			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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 / 35 (0.00%)	0 / 43 (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	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Bronchial obstruction			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Pleural effusion			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Stridor			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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 / 1	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Post procedural haemorrhage			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Procedural pain			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Wound complication			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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			
Brain oedema			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Dizziness			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Hemiplegia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Seizure			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Spinal cord compression			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Syncope			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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 / 35 (0.00%)	0 / 43 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (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
Ascites			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Dysphagia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Mouth haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Nausea			

subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Obstruction gastric			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Oesophageal haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Oesophageal stenosis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Vomiting			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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 failure			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Hepatic haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Jaundice cholestatic			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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			
Urinary incontinence			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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 / 35 (0.00%)	0 / 43 (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
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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			
Arthralgia			

subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 35 (5.71%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated myositis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (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
Neck pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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			
Appendicitis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Atypical pneumonia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Bacterial sepsis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
COVID-19 pneumonia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Cellulitis			

subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Clostridium difficile infection			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Escherichia bacteraemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Pneumonia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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 mycoplasmal			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (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
Rhinovirus infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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
Sepsis			

subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Skin infection			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Soft tissue infection			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Urinary tract infection			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	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
Hyponatraemia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (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

Serious adverse events	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 240 mg	Alomfilimab 80 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	2 / 5 (40.00%)	3 / 7 (42.86%)
number of deaths (all causes)	5	4	5
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 / 5 (0.00%)	1 / 7 (14.29%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (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			
Urinary incontinence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (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
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bacterial sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 mycoplasmal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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 / 5 (0.00%)	0 / 7 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
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	Alomfilimab 24 mg	Alomfilimab 8 mg	Alomfilimab 2.4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)	3 / 10 (30.00%)	1 / 5 (20.00%)
number of deaths (all causes)	7	6	4
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (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
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (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
Post procedural haemorrhage			

subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (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
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	2 / 10 (20.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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 failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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			
Urinary incontinence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (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
Urinary tract obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (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
Immune-mediated myositis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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 mycoplasmal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Alomfilimab 0.8 mg	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
number of deaths (all causes)	2	1	1

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated myositis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	1 / 5 (20.00%)	6 / 15 (40.00%)
number of deaths (all causes)	1	2	10

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 6 (33.33%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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			
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (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			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			

subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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			
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated myositis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 mycoplasmal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
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	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	3 / 9 (33.33%)	1 / 5 (20.00%)
number of deaths (all causes)	1	3	3

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (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
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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			
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			

subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			

subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (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
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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 failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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			
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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 myositis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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 mycoplasmal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
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	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 14 (14.29%)	1 / 7 (14.29%)	2 / 14 (14.29%)
number of deaths (all causes)	7	5	10

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary incontinence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated myositis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 8 (50.00%)	1 / 3 (33.33%)	
number of deaths (all causes)	4	2	

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour associated fever			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stridor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Odynophagia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Urinary incontinence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated myositis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Alomfilimab 8 mg + Atezolizumab	Alomfilimab 2.4 mg + Atezolizumab	Alomfilimab 24 mg + Atezolizumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 35 (97.14%)	39 / 43 (90.70%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour ulceration			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour cavitation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Hypotension			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			

subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 35 (5.71%)	3 / 43 (6.98%)	0 / 9 (0.00%)
occurrences (all)	2	3	0
Fatigue			
subjects affected / exposed	10 / 35 (28.57%)	8 / 43 (18.60%)	1 / 9 (11.11%)
occurrences (all)	11	10	1
Influenza like illness			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Malaise			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 35 (0.00%)	3 / 43 (6.98%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Chest pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Oedema peripheral			
subjects affected / exposed	2 / 35 (5.71%)	3 / 43 (6.98%)	0 / 9 (0.00%)
occurrences (all)	2	3	0
Non-cardiac chest pain			

subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	10 / 35 (28.57%)	9 / 43 (20.93%)	2 / 9 (22.22%)
occurrences (all)	13	15	3
Swelling			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	5 / 35 (14.29%)	7 / 43 (16.28%)	0 / 9 (0.00%)
occurrences (all)	7	10	0
Epistaxis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			

subjects affected / exposed	8 / 35 (22.86%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences (all)	11	1	1
Haemoptysis			
subjects affected / exposed	2 / 35 (5.71%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Immune-mediated lung disease			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Paranasal sinus haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Sinus congestion			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 35 (5.71%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	2	2	0
Confusional state			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Depression			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Terminal insomnia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Investigations			
Amylase increased			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	1	3	1
Alanine aminotransferase increased			
subjects affected / exposed	2 / 35 (5.71%)	3 / 43 (6.98%)	0 / 9 (0.00%)
occurrences (all)	5	5	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 35 (14.29%)	5 / 43 (11.63%)	1 / 9 (11.11%)
occurrences (all)	10	6	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Blood creatinine increased			
subjects affected / exposed	2 / 35 (5.71%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	2	3	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Blood cholesterol increased			

subjects affected / exposed	2 / 35 (5.71%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	2	2	0
Blood bilirubin increased			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Body temperature decreased			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood pressure increased			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 35 (5.71%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	5	2	1
International normalised ratio increased			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Lipase decreased			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	2 / 35 (5.71%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Platelet count decreased			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 35 (5.71%)	4 / 43 (9.30%)	1 / 9 (11.11%)
occurrences (all)	3	6	3
Lipase increased			
subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
White blood cell count decreased			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	8 / 35 (22.86%)	9 / 43 (20.93%)	5 / 9 (55.56%)
occurrences (all)	8	14	5
Lumbar vertebral fracture			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stoma site inflammation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pneumothorax			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vascular access complication			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Coordination abnormal			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aphasia			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hemianopia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 35 (8.57%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	3	4	2
Dysmetria			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Migraine			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hemianopia homonymous			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Sinus headache			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 35 (31.43%)	9 / 43 (20.93%)	3 / 9 (33.33%)
occurrences (all)	20	15	3
Eosinophilia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	3	4	0
Lymph node pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	5 / 35 (14.29%)	3 / 43 (6.98%)	2 / 9 (22.22%)
occurrences (all)	5	4	4

Neutropenia			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Neutrophilia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Periorbital oedema			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Periorbital pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	3 / 35 (8.57%)	5 / 43 (11.63%)	1 / 9 (11.11%)
occurrences (all)	4	7	1
Abdominal pain upper			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	2	3	0
Ascites			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 35 (5.71%)	3 / 43 (6.98%)	1 / 9 (11.11%)
occurrences (all)	2	3	1
Abdominal tenderness			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Dry mouth			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	5 / 35 (14.29%)	5 / 43 (11.63%)	2 / 9 (22.22%)
occurrences (all)	7	9	3
Dysphagia			
subjects affected / exposed	4 / 35 (11.43%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	5	1	0
Eructation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Flatulence			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 35 (8.57%)	3 / 43 (6.98%)	0 / 9 (0.00%)
occurrences (all)	3	3	0
Toothache			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Mouth haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 35 (0.00%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Stomatitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 35 (11.43%)	3 / 43 (6.98%)	3 / 9 (33.33%)
occurrences (all)	6	4	5
Odynophagia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			

subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Dermatitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	4 / 35 (11.43%)	3 / 43 (6.98%)	1 / 9 (11.11%)
occurrences (all)	4	3	1
Eczema			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	2 / 35 (5.71%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Skin plaque			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	4 / 35 (11.43%)	4 / 43 (9.30%)	1 / 9 (11.11%)
occurrences (all)	4	4	1
Rash vesicular			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Rash papular			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Haematuria			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary hesitation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hypothyroidism			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Bone pain			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	4 / 35 (11.43%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	6	3	2
Back pain			
subjects affected / exposed	2 / 35 (5.71%)	5 / 43 (11.63%)	2 / 9 (22.22%)
occurrences (all)	2	6	2
Muscle spasms			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Muscular weakness			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Musculoskeletal pain			
subjects affected / exposed	2 / 35 (5.71%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Myalgia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	1 / 9 (11.11%)
occurrences (all)	0	3	1
Osteoporosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	2	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	2 / 35 (5.71%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	2	2	0
Pain in jaw			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rhabdomyolysis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

COVID-19			
subjects affected / exposed	0 / 35 (0.00%)	3 / 43 (6.98%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Candida infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	1	3	0
Herpes zoster reactivation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 35 (5.71%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Hordeolum			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Tinea pedis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 35 (2.86%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	1	4	0
Tooth infection			
subjects affected / exposed	0 / 35 (0.00%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	2 / 35 (5.71%)	5 / 43 (11.63%)	1 / 9 (11.11%)
occurrences (all)	4	7	1

Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	1 / 35 (2.86%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Decreased appetite			
subjects affected / exposed	7 / 35 (20.00%)	0 / 43 (0.00%)	1 / 9 (11.11%)
occurrences (all)	9	0	1
Hypercholesterolaemia			
subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 35 (5.71%)	2 / 43 (4.65%)	1 / 9 (11.11%)
occurrences (all)	2	2	1
Hypocalcaemia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			

subjects affected / exposed	0 / 35 (0.00%)	0 / 43 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 35 (0.00%)	3 / 43 (6.98%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Iron deficiency			
subjects affected / exposed	2 / 35 (5.71%)	1 / 43 (2.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Hyponatraemia			
subjects affected / exposed	2 / 35 (5.71%)	2 / 43 (4.65%)	0 / 9 (0.00%)
occurrences (all)	2	2	0

Non-serious adverse events	Alomfilimab 0.8 mg + Atezolizumab	Alomfilimab 240 mg	Alomfilimab 80 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	5 / 5 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour cavitation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	3
Fatigue			
subjects affected / exposed	1 / 5 (20.00%)	3 / 5 (60.00%)	0 / 7 (0.00%)
occurrences (all)	1	4	0
Influenza like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Chest pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune-mediated lung disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Terminal insomnia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	2 / 5 (40.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Body temperature decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fall			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	3 / 5 (60.00%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Tooth fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma site inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Procedural pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Coordination abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemianopia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Dysmetria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemianopia homonymous			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypersomnia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 5 (40.00%)	1 / 7 (14.29%)
occurrences (all)	0	3	4
Eosinophilia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Iron deficiency anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Abdominal tenderness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eructation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	0 / 5 (0.00%)	2 / 7 (28.57%)
occurrences (all)	3	0	2
Toothache			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Odynophagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	4
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	2 / 5 (40.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Skin plaque			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 5 (40.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	2
Rash vesicular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal pain			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Catheter site infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster reactivation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Soft tissue infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Decreased appetite			
subjects affected / exposed	2 / 5 (40.00%)	2 / 5 (40.00%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Alomfilimab 24 mg	Alomfilimab 8 mg	Alomfilimab 2.4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 8 (87.50%)	7 / 10 (70.00%)	4 / 5 (80.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour cavitation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	2 / 8 (25.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	2 / 8 (25.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 8 (0.00%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Immune-mediated lung disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Terminal insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Body temperature decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone			

increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 8 (12.50%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stoma site inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vascular access complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 8 (37.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Coordination abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hemianopia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Dysmetria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hemianopia homonymous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 8 (37.50%)	2 / 10 (20.00%)	1 / 5 (20.00%)
occurrences (all)	3	2	1
Eosinophilia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	2 / 8 (25.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Abdominal tenderness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	3 / 8 (37.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	4	0	0
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 8 (37.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Odynophagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Alopecia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Skin plaque			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Chromaturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Trismus			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster reactivation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dehydration			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 8 (25.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Cachexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			

subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Alomfilimab 0.8 mg	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tumour ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tumour cavitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Epistaxis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune-mediated lung disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Terminal insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Body temperature decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lipase decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stoma site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Procedural pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 4 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Coordination abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hemianopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Dysmetria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hemianopia homonymous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Eosinophilia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Lymph node pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Periorbital pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hypothyroidism			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Eye infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes zoster reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT TNBC	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	5 / 5 (100.00%)	15 / 15 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Uterine leiomyoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tumour ulceration			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Tumour cavitation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Hypotension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 5 (20.00%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			

subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 6 (50.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immune-mediated lung disease			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pneumothorax			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Paranasal sinus haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Terminal insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Investigations			
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	3 / 15 (20.00%)
occurrences (all)	3	0	3
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Blood cholesterol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Body temperature decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Blood pressure increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Fibrin D dimer increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	3
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	3 / 15 (20.00%)
occurrences (all)	0	0	3
Lipase decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	3
Lipase increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	4 / 15 (26.67%)
occurrences (all)	0	0	7
Lumbar vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Stoma site inflammation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Procedural pneumothorax			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Coordination abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hemianopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dysmetria			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hemianopia homonymous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tremor			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	2 / 5 (40.00%)	5 / 15 (33.33%)
occurrences (all)	1	2	8
Eosinophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 5 (40.00%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neutrophilia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Periorbital oedema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Periorbital pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Constipation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Abdominal tenderness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Nausea			

subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Rash vesicular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1

Dysuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hypothyroidism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	2
Back pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Muscle spasms			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			

subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	2
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Herpes zoster reactivation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Decreased appetite			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Hypercholesterolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Cachexia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 5 (20.00%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Hyperlipasaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	2 / 5 (40.00%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 5 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2

Non-serious adverse events	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 PT PC	Alomfilimab 80 mg + Atezolizumab	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve HNSCC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	9 / 9 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour ulceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour cavitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tumour associated fever			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infected neoplasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Jugular vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	2 / 9 (22.22%)	2 / 5 (40.00%)
occurrences (all)	1	2	2
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 9 (22.22%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune-mediated lung disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paranasal sinus haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Terminal insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 2 (0.00%)	2 / 9 (22.22%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Body temperature decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			

subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Lipase decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 2 (50.00%)	6 / 9 (66.67%)	1 / 5 (20.00%)
occurrences (all)	1	6	1
Lumbar vertebral fracture			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tooth fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stoma site inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Coordination abnormal			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hemianopia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysmetria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hemianopia homonymous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Peripheral motor neuropathy			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sinus headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	3 / 9 (33.33%)	1 / 5 (20.00%)
occurrences (all)	2	5	2
Eosinophilia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 9 (22.22%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Neutrophilia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 2 (50.00%)	2 / 9 (22.22%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Abdominal tenderness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	2 / 9 (22.22%)	1 / 5 (20.00%)
occurrences (all)	0	2	1
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	2 / 9 (22.22%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	2 / 9 (22.22%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			

subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Muscle tightness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Osteoporosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Cystitis			

subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	1 / 5 (20.00%)
occurrences (all)	0	1	2
Candida infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster reactivation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Tooth infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hyperlipasaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 9 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 9 (11.11%)	2 / 5 (40.00%)
occurrences (all)	0	1	4

Non-serious adverse events	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 2.4 mg + Atezolizumab in Anti-PD-(L)1 Naïve TNBC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 Naïve PC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	7 / 7 (100.00%)	13 / 14 (92.86%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Tumour ulceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tumour cavitation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0

Infected neoplasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Lymphoedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Superficial vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	3 / 14 (21.43%)	1 / 7 (14.29%)	6 / 14 (42.86%)
occurrences (all)	3	1	7
Influenza like illness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	2 / 14 (14.29%)
occurrences (all)	2	0	2
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	5	0	0
Swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	2 / 14 (14.29%)
occurrences (all)	2	0	2
Haemoptysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Immune-mediated lung disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Paranasal sinus haemorrhage			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Terminal insomnia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	3
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 14 (21.43%)	0 / 7 (0.00%)	3 / 14 (21.43%)
occurrences (all)	3	0	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Blood creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 14 (14.29%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	4	1	0
Blood cholesterol increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Body temperature decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
International normalised ratio increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lipase decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Platelet count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	3 / 14 (21.43%)
occurrences (all)	2	0	6
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed	2 / 14 (14.29%)	1 / 7 (14.29%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	4 / 14 (28.57%)	0 / 7 (0.00%)	2 / 14 (14.29%)
occurrences (all)	4	0	3
Lumbar vertebral fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tooth fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Stoma site inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Procedural pneumothorax			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Coordination abnormal			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Aphasia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hemianopia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 14 (7.14%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Dysmetria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hemianopia homonymous			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	6	0	2
Eosinophilia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	4 / 14 (28.57%)	2 / 7 (28.57%)	0 / 14 (0.00%)
occurrences (all)	7	4	0
Lymph node pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 7 (14.29%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Neutropenia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	3	1	0
Neutrophilia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Vertigo			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Periorbital pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	2 / 14 (14.29%)
occurrences (all)	0	1	2
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Abdominal tenderness			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 14 (14.29%)	1 / 7 (14.29%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	2
Toothache			

subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Odynophagia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	2 / 14 (14.29%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	3	1	0
Eczema			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Skin plaque			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Haematuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	2 / 14 (14.29%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Immune-mediated hypothyroidism			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Muscle spasms			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 14 (0.00%)	2 / 7 (28.57%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Trismus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Pain in jaw			

subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Bacteriuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Herpes zoster reactivation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0

Mucosal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Soft tissue infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	5 / 14 (35.71%)
occurrences (all)	1	0	5
Hypercholesterolaemia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Cachexia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Hypoalbuminaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	3	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Alomfilimab 24 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	Alomfilimab 8 mg + Atezolizumab in Anti-PD-(L)1 PT HNSCC	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	2 / 3 (66.67%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Uterine leiomyoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Tumour ulceration			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Tumour cavitation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Tumour associated fever			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Infected neoplasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

Lymphoedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Superficial vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	4 / 8 (50.00%)	1 / 3 (33.33%)	
occurrences (all)	4	1	
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Swelling			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pelvic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	2	
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Immune-mediated lung disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Paranasal sinus haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Sinus congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	2	
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Terminal insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Investigations			
Amylase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Blood cholesterol increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Blood bilirubin increased				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Body temperature decreased				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Blood thyroid stimulating hormone increased				
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)		
occurrences (all)	0	1		
Blood pressure increased				
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)		
occurrences (all)	0	1		
Cardiac murmur				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Blood lactate dehydrogenase increased				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Fibrin D dimer increased				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Gamma-glutamyltransferase				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
International normalised ratio increased				
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Lipase decreased				

subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Lipase increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	5	
White blood cell count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Post-traumatic pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Lumbar vertebral fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Procedural pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Stoma site inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Spinal fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Procedural pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Vascular access complication			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	2	
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
Coordination abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Aphasia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hemianopia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	2	
Dysmetria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Migraine			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hemianopia homonymous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypersomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Peripheral motor neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Sinus headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	2	
Eosinophilia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Lymph node pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Neutrophilia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypoacusis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Periorbital oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Periorbital pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Abdominal tenderness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Aphthous ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Eructation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Flatulence			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Melaena			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Mouth haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Odynophagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Dry skin			

subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Eczema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Skin plaque			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Rash vesicular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rash papular			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Skin ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Hydronephrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Urinary hesitation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Adrenal insufficiency			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Immune-mediated hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Bone pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Muscle tightness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Arthralgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Osteoporosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Neck pain			

subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Trismus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pain in jaw			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Rhabdomyolysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Catheter site infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Bacteriuria			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Eye infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Folliculitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Candida infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Herpes zoster reactivation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Mucosal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
Hordeolum			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 3 (33.33%)	
occurrences (all)	1	1	

Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Tinea pedis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Tooth abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Soft tissue infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Vaginal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 8 (25.00%)	1 / 3 (33.33%)	
occurrences (all)	2	1	
Tooth infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	

Metabolism and nutrition disorders			
Hyperamylasaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Decreased appetite			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Hypercholesterolaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 3 (0.00%)	
occurrences (all)	2	0	
Cachexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hyperlipasaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Hypokalaemia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 3 (33.33%)	
occurrences (all)	0	1	
Iron deficiency			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Hyponatraemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 3 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 November 2018	Clinical Study Protocol Version 2.0.
14 January 2019	Clinical Study Protocol Version 3.0.
08 May 2019	Clinical Study Protocol Version 4.0.
28 July 2020	Clinical Study Protocol Version 5.0.
07 May 2021	Clinical Study Protocol Version 6.0.
10 November 2021	Clinical Study Protocol Version 7.0.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported